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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

In re LIDODERM ANTITRUST LITIGATION This Document Relates to All Cases	MDL Docket No. 14-md-02521-WHO **DEFENDANTS' NOTICE OF JOINT MOTION, JOINT MOTION, AND MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF JOINT MOTION TO DISMISS PLAINTIFFS' COMPLAINTS** Date: October 8, 2014 Time: 2:00 p.m. Courtroom: Courtroom 2, 17th Floor Before: Hon.William H. Orrick

NOTICE OF MOTION AND MOTION TO DISMISS

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

Please take notice that on October 8, 2014, at 2:00 p.m., or as soon thereafter as the matter may be heard by the Court, at the courtroom of the Honorable William H. Orrick, Courtroom 2, 17th Floor, United States District Court, 450 Golden Gate Avenue, San Francisco, California, Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Actavis, plc, (together, "Watson"); Anda, Inc., Anda Pharmaceuticals, Inc., and Valmed Pharmaceuticals, (together, "Anda"); Endo Pharmaceuticals Inc. ("Endo"); and Teikoku Pharma USA and Teikoku Seiyaku Co. (together, "Teikoku") will and hereby do move the Court, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, for an order dismissing the Direct Purchaser Plaintiffs' Consolidated Amended Class Action Complaint, the End-Payor Plaintiffs' Consolidated Amended Complaint, and the First Amended Complaint by the Government Employees Health Association (collectively, the "Amended Complaints") with prejudice. This motion to dismiss is brought on the grounds that the claims in the Amended Complaints fail to state a claim under federal or state antitrust laws against Defendants upon which relief can be granted.

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INTRODUCTION

Plaintiffs challenge a Settlement and License Agreement entered into between Endo and Teikoku (together the "Brand Defendants"), on the one hand, and Watson, on the other hand, that resolved patent litigation relating to Lidoderm (the "Lidoderm Settlement"). Watson sought to introduce a generic version of Lidoderm pursuant to the procedures established by the Hatch-Waxman Act, and the Brand Defendants sued Watson for infringement of their patents. After more than two years of hard-fought litigation without a decision, with a second patent case in its infancy, and a long-standing Citizen Petition effectively preventing FDA approval of any generic product, the parties settled. Neither Endo nor Teikoku paid Watson anything to settle. Instead, the Brand Defendants provided Watson with a license to introduce its generic version of Lidoderm on September 15, 2013, more than two years earlier than the latest-expiring patent covering Lidoderm. And because the Citizen Petition was effectively blocking approval of Watson's generic, and could continue to do so indefinitely, the Brand Defendants agreed to provide Watson with Lidoderm product to sell in competition with Endo beginning on January 1, 2013, almost three years prior to when the last patent on Lidoderm was due to expire. Plaintiffs now file these actions alleging that the Lidoderm Settlement involved "reverse payments" of "hundreds of millions of dollars" by the Brand Defendants to Watson in exchange for Watson's agreement not to compete in the market for Lidoderm. (DPP CAC ¶ 2; EPP CAC ¶ 1; GEHA FAC ¶ 109.)[1] Plaintiffs are wrong.

This Court should dismiss all of Plaintiffs' federal antitrust claims for five independent reasons, which (among other grounds) also compel dismissal of Plaintiffs' state law claims. *First*, contrary to Plaintiffs' assertion, the Lidoderm Settlement is not *per se* unlawful. The Supreme Court's decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), explicitly rejected a rule of

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[1] This brief uses the following abbreviated citations to the Amended Complaints:

- "DPP CAC" refers to the Direct Purchaser Plaintiffs' Consolidated Amended Class Action Complaint, filed on June 13, 2014, at Docket No. 70;
- "EPP CAC" refers to the End-Payor Plaintiffs' Consolidated Amended Complaint, filed on June 13, 2014, at Docket No. 72; and
- "GEHA FAC" refers to the First Amended Complaint filed by Government Employees Health Association on June 13, 2014, at Docket No. 71.

presumptive illegality for reverse payment settlements. *Actavis* establishes that the only circumstance in which a "reverse payment" patent settlement even arguably raises antitrust concerns is when it contains a large, unjustified payment to the generic in exchange for the generic's agreement to stay off the market. And *even then*, plaintiffs must establish that the settlement is anticompetitive—*i.e.*, that it is an *unreasonable* restraint of trade—under the rule of reason. *See id.* at 2234-37.

Second, Plaintiffs cannot plausibly allege that the Lidoderm Settlement contained any reverse payments. Instead, Plaintiffs claim that Watson received value in the form of (1) branded product provided by Endo to Watson, the value of which Watson could only have realized by selling the product in competition with Endo, and (2) an agreement by Endo not to market its own authorized generic version of Lidoderm or to license another generic company to market competing products for a limited period of time. Plaintiffs' assertions turn *Actavis* on its head by claiming that the very sales Watson makes—and by which early entry and competition were achieved in the first place—could *themselves* be an impermissible payment for delay. These aspects of the Lidoderm Settlement are not payments within the meaning of *Actavis*, because Watson realized no value from the settlement unless and until it *entered* the market with a competing product. Such a *procompetitive* benefit stands in stark contrast to *Actavis*' direction that only settlements where the patent holder pays a challenger to "stay out" of the market ought to be scrutinized.

Third, on its face, the Lidoderm Settlement was a reasonable compromise of the patent suit, and Plaintiffs' Amended Complaints do not plausibly allege that it was unreasonable. Indeed, any such attempt would be implausible given the regulatory obstacles and litigation risks faced by Watson at the time of the settlement. Far from delaying competition, the Lidoderm Settlement enhanced competition by guaranteeing entry early, and ensuring that Watson would have product to sell in competition with Endo while Watson awaited FDA approval for its generic product.

Fourth, Plaintiffs have not sufficiently alleged any injury caused by the Lidoderm Settlement, and on this basis alone, the Court should dismiss Plaintiffs' claims with prejudice. In particular, Plaintiffs have not plausibly alleged that generic entry would have occurred prior to

January 1, 2013, or even the license date of September 15, 2013.

Fifth, Plaintiffs cannot establish monopolization or attempted monopolization because they advance a theory of *shared* monopoly power between Endo and Teikoku instead of conduct by a single firm.

Finally, claims arising under state laws must be dismissed for lack of standing and for various reasons particular to those laws.

BACKGROUND

I. REGULATORY FRAMEWORK

These cases arise at the intersection of patent law and the complex statutory and regulatory scheme governing the production and marketing of pharmaceutical products, including generic pharmaceutical products—the Hatch-Waxman Act. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 ("Hatch-Waxman Act"). (DPP CAC ¶¶ 31-41; EPP CAC ¶¶ 38-50; GEHA FAC ¶¶ 33-45.) The Hatch-Waxman Act seeks to balance the intellectual property rights of innovator drug companies (or "brand manufacturers") with the legislative desire to encourage generic competition for pharmaceutical products. *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). It does this several ways, including by recognizing the patent rights—such as market exclusivity—of brand manufacturers, and by providing additional potential exclusivities to such companies for developing innovative drugs. The Hatch-Waxman Act also permits early patent challenges from proposed generic products and streamlines the process for brand manufacturers and generic applicants to resolve patent disputes and determine whether or not the generic manufacturer can lawfully introduce its competing generic product to market.

The Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399 requires all new drugs to be approved by the U.S. Food and Drug Administration ("FDA") before they are introduced into commerce. 21 U.S.C. § 355(a)[2] The FDCA provides two major paths for

[2] Section 505 of the FDCA, 21 U.S.C. § 355, was amended in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, §§ 1101-1103, 117 Stat. 2066, 2448-61 (codified at 21 U.S.C. § 355 (2006)), and has been further amended since then.

obtaining FDA approval: (1) the rigorous new drug application ("NDA"); and (2) the abbreviated new drug application ("ANDA") for generic products, set forth in 21 U.S.C. § 355(j). A brand manufacturer seeking to introduce a new drug to the marketplace must submit an NDA to obtain FDA approval. The FDA will not approve an NDA until the applicant demonstrates that the drug is safe and effective for its intended use(s). *See id.* § 355(d). Upon approval of an NDA, the NDA holder is required to identify patents covering the approved drug. The FDA lists the patents in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, published and updated by the FDA pursuant to Section 505 of the FDCA, 21 U.S.C. § 355 (commonly referred to as the "Orange Book"). *See id.* § 355(j)(2)(A)(vii), (7).

Under Hatch-Waxman, ANDA applicants are relieved of the obligation to perform extensive testing demonstrating the safety and effectiveness of their drug. Instead, a drug that follows the ANDA process relies on research conducted by the marketer of an approved NDA product (also known as the reference listed drug or "RLD") in order to meet FDA approval requirements: ANDA applicants must submit information showing that the conditions of use, active ingredient, dosage form, strength, route of administration, and labeling of the generic drug are the same as those of the RLD that was previously approved. *See id.* § 355(b)(1), (2), (j)(2)(A)(i)-(v), (7). In other words, to secure FDA approval for an ANDA, a generic manufacturer must demonstrate that the proposed generic drug is "bioequivalent" to the corresponding NDA product. *Id.* § 355(j)(2)(A)(iv). To protect the patent rights of NDA holders, ANDA applicants must assure the FDA that their proposed generic drug will not infringe any patents listed by the NDA holder in the Orange Book. Thus, for each relevant patent in the Orange Book, ANDA applicants must certify that: (i) no such patent information has been filed; (ii) the relevant patent has expired; (iii) the generic will not market its product until the date on which such patent will expire; or (iv) the relevant patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. *Id.*

To streamline patent challenges and allow for a judicial determination on the merits of the patent challenge prior to any infringing sales, the filing of the fourth type of certification, a "Paragraph IV Certification," is treated as a technical act of patent infringement by the ANDA

applicant that triggers certain notice requirements. *See* 35 U.S.C. § 271(e)(2)(A). In particular, the FDCA requires the ANDA applicant to notify the patent holder of the filing of a Paragraph IV Certification, *see* 21 U.S.C. § 355(j)(2)(B), and if the patent holder brings a patent infringement suit within 45 days of receipt of the notice, the FDCA bars approval of the applicant's ANDA—or any other ANDA relating to the drug—for thirty months, unless the applicant wins the suit earlier. *Id.* § 355(j)(5)(B)(iii). Even after the statutory stay expires, FDA approval of the ANDA does not immunize the generic company from potential liability for patent infringement. Although the ANDA applicant may begin selling its product upon receipt of final FDA approval, it does so at the risk of potentially substantial infringement damages, including treble damages for willful infringement, which often exceed the generic company's revenues from sales. Such damages could bankrupt a generic company if it launched at risk and was later found to have infringed a patent on the RLD. *See Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829, 833 (Fed Cir. 1999). These risks prompted Representative Waxman, one of the namesakes of the Hatch-Waxman Act, to acknowledge that "[t]he facts of life are that a generic drug manufacturer will await, as a practical matter, until the decision of a court on a patent challenge before that manufacturer markets a generic drug." 130 Cong. Rec. H9115 (daily ed. Sept. 6, 1984) (statement of Rep. Waxman).

Hatch-Waxman litigation, like all patent litigation, is expensive and uncertain in outcome. To encourage generic manufacturers to expend the resources to develop a generic version of a drug, and make a Paragraph IV Certification despite the threat of costly litigation, the FDA may not approve subsequent ANDAs until 180 days from either "the date of the first commercial marketing of the drug" by the first paragraph IV applicant or the date on which an applicant wins a patent infringement suit involving the relevant patent, whichever is earlier. 21 U.S.C. § 355(j)(5)(B)(iv). This gives the first generic to challenge the NDA holder's patents a "180-day exclusivity period," *id.*, during which the applicant has the right to sell its product without competition from other generic manufacturers.

Another regulatory procedure pertinent here is the FDA's Citizen Petition process. A Citizen Petition is the means by which an individual or entity may express concerns to the FDA about safety, scientific, or legal issues regarding a product, including a request that the FDA take,

or refrain from taking, any administrative action. *See* 21 C.F.R. § 10.30 (2014). For example, a Citizen Petition could request that the FDA impose additional requirements on ANDA filers that reference a particular RLD. In circumstances where a Citizen Petition seeks additional regulatory scrutiny of certain ANDAs, at all times relevant here "the FDA had a well-known practice of withholding both tentative and final ANDA approval until after its consideration of and response to [such] a citizen petition was complete." (EPP CAC ¶ 49.)

II. LIDODERM PATENT LITIGATION AND SETTLEMENT

These actions arise out of the decision by Endo, Teikoku, and Watson to settle their patent litigation relating to Lidoderm. Lidoderm (lidocaine patch 5%) is one of several drugs approved by the FDA to relieve the pain of post-herpetic neuralgia.[3] (DPP CAC ¶ 55; EPP CAC ¶ 63; GEHA FAC ¶ 54.) Lidoderm was approved by the FDA in 1999 and has been sold in the United States by Endo since that time under a license agreement with Teikoku. (DPP CAC ¶ 57; EPP CAC ¶¶ 64-65; GEHA FAC ¶¶ 55-56.) Endo and Teikoku have owned or licensed several patents for Lidoderm, including:

- U.S. Patent No. 5,827,529 (filed June 10, 1994) (the '529 Patent), due to expire October 27, 2015;
- U.S. Patent No. 5,741,510 (filed Apr. 8, 1996) (the '510 Patent), U.S. Patent No. 6,096,333 (filed Oct. 8, 1997) (the '333 Patent), and U.S. Patent No. 6,096,334 (filed Dec. 14, 1998) (the '334 Patent) (together, the "Rolf Patents"), which expired on March 30, 2014; and

[3] The facts set forth herein are taken from the Amended Complaints, from documents incorporated by reference or integral to the Amended Complaints, or from documents that may be judicially noticed. *See, e.g., Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) ("courts must consider the complaint in its entirety, as well as . . . documents incorporated into the complaint by reference, and matters of which a court may take judicial notice" when ruling on Rule 12(b)(6) motions); *Barnes v. Windsor Sec. LLC*, No. 13-cv-01878-WHO, 2013 WL 4426244, at *2 (N.D. Cal. Aug. 15, 2013) (Orrick, J.) ("Under the 'incorporation by reference' doctrine . . . a court may 'consider materials incorporated into the complaint or matters of public record,' including 'documents in situations where the complaint necessarily relies upon a document or the contents of the document are alleged in a complaint, the document's authenticity is not in question and there are no disputed issues as to the document's relevance.'" (quoting *Coto Settlement v. Eisenberg*, 593 F.3d 1031, 1038 (9th Cir. 2010))). Rule 201 of the Federal Rules of Evidence provides that, upon a party's request, a court must take judicial notice of "a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined form sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2), (c)(2). Defendants have filed a Request for Judicial Notice in Support of Joint Motion to Dismiss Plaintiffs' Complaints, and a Declaration of Karen Hoffman Lent in Support Thereof ("RJN"), contemporaneously herewith requesting that the Court take judicial notice of RJN Exhibits A-E.

- U.S. Patent No. 5,601,838 (filed May 18, 1990) (the '838 Patent) and U.S. Patent No. 5,411,738 (filed Feb. 16, 1994) (the '738 Patent) (together, the "Hind Patents"), which expired on May 2, 2012.

(DPP CAC ¶¶ 58-70; EPP CAC ¶¶ 66-76; GEHA FAC ¶¶ 66-76.)

On December 18, 2006, Endo submitted a Citizen Petition to the FDA, requesting that the agency require any ANDA filer seeking approval of a generic Lidoderm to conduct actual clinical trials demonstrating bioequivalence with Lidoderm, rather than the pharmacokinetic studies traditionally required for generic drugs. Endo Pharm. Inc., Citizen Petition at 1-3, FDA Docket No. 2006P-0522 (Dec. 18, 2006), *available at* http://www.fda.gov/ohrms/dockets/dockets/06p0522/06p-0522-cp00001-01-vol1.pdf.[4] (EPP CAC ¶¶ 49, 101; GEHA FAC ¶ 6.) Endo contended that pharmacokinetic studies—which measure the level of a drug in the bloodstream—are not enough to demonstrate that generic Lidoderm was bioequivalent to the branded drug in light of Lidoderm's unique qualities. Instead, Endo argued that the effectiveness of locally active topical products such as Lidoderm could only be demonstrated through the use of clinical endpoint studies. Citizen Petition, *supra*, at 1-3. On August 29, 2007, Endo amended its Citizen Petition to request that the FDA withdraw earlier guidance it had issued on the bioequivalence of patch products, and convene a meeting with FDA advisory committees to discuss appropriate methods for demonstrating bioequivalence. RJN Ex. E, Endo Pharm. Inc., Amended Citizen Petition at 1, FDA Docket No. 2006P-0522 (Aug. 29, 2007), *available at* http://www.fda.gov/ohrms/dockets/dockets/06p0522/06p-0522-amd0001-02-vol2.pdf. (EPP CAC ¶¶ 49, 101.)

On November 13, 2009, Watson filed ANDA No. 20-675 with the FDA, seeking approval to market a generic lidocaine 5% patch. (DPP CAC ¶ 71; EPP CAC ¶ 77; GEHA FAC ¶ 70.) Watson's ANDA included a Paragraph IV Certification as to the '529 Patent. On or about January

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[4] For purposes of deciding this motion to dismiss, the Court should consider Endo's Citizen Petition filings. First, they qualify for judicial notice because they are public documents posted on the FDA website, which is a source whose accuracy cannot reasonably be questioned. *See* Fed. R. Evid. 201(b)(2); *see also Novartis Pharms., Corp. v. Wockhardt USA LLC*, No. 12-cv-3967, 2013 WL 5770539, at *4-5 (D.N.J. Oct. 23, 2013) (taking judicial notice of the FDA's response to a citizen petition). Second, they are incorporated by reference in both the EPP CAC and the GEHA FAC. *See, e.g., Barnes*, 2013 WL 4426244, at *2.

14, 2010, Watson notified Teikoku of its ANDA filing. (DPP CAC ¶¶ 71-72; EPP CAC ¶ 77; GEHA FAC ¶¶ 70-71.) On February 19, 2010, Endo and Teikoku filed an action against Watson in the District of Delaware for infringement of the '529 Patent, captioned *Endo Pharmaceuticals Inc., et al. v. Watson Laboratories, Inc.*, No. 1:10-cv-138-GMS (D. Del. filed Feb. 19, 2010) (the "'529 Lawsuit"). (DPP CAC ¶ 76; EPP CAC ¶ 81; GEHA CAC ¶ 76.) The '529 Lawsuit triggered an automatic 30-month stay on FDA approval of generic Lidoderm until mid-July 2012, *i.e.*, thirty months from Teikoku's receipt of Watson's Paragraph IV notice on the '529 Patent. (DPP CAC ¶ 76; EPP CAC ¶ 81; GEHA FAC ¶ 76.)

While the '529 Lawsuit and Citizen Petition were both pending, Endo acquired the Rolf Patents and added one of these—the '510 Patent—to the patents listed for Lidoderm in the Orange Book.[5] Endo then filed a second suit against Watson in Delaware district court on June 29, 2011, captioned *Endo Pharmaceuticals Inc., et al. v. Watson Laboratories, Inc.*, No. 11-cv-575-GMS (D. Del. filed June 29, 2011) (the "Rolf Lawsuit"), alleging infringement of the Rolf Patents. (DPP CAC ¶ 78; EPP CAC ¶ 82; GEHA FAC ¶ 78.) On March 12, 2012, Endo filed what would be its final amendment to the Citizen Petition, submitting additional support for its position that clinical endpoint studies should be required before approving any generic. Endo Pharm., Amendment, FDA Docket No. FDA-2006-P-0346-0006 (formerly 2006P-0522) (Mar. 12, 2012), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2006-P-0346-0016. (EPP CAC ¶¶ 49, 101.)

On May 28, 2012, Endo, Teikoku, and Watson settled the '529 Lawsuit and the Rolf Lawsuit. (DPP CAC ¶ 93; EPP CAC ¶¶ 101, 103; GEHA FAC ¶ 96.)[6] At the time of the settlement the '529 Lawsuit had been litigated for over two years but had not yet been decided; and the Rolf Lawsuit was in the early stages of litigation. (DPP CAC ¶ 89; EPP CAC ¶ 96; GEHA FAC ¶¶ 79, 89.) In addition, the Citizen Petition remained pending (and had been for nearly six

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[5] Because the '510 Patent was not listed in the Orange Book at the time Watson submitted its ANDA, Watson was not required to make a certification as to the patent in its ANDA. (DPP CAC ¶¶ 70, 79; EPP CAC ¶¶ 76, 79; GEHA FAC ¶¶ 69, 74.)

[6] RJN Ex. A, Lidoderm Settlement. The Court is "entitled to take notice of the full contents of" the Lidoderm Settlement because it is "referenced in the complaint." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 568 n.13 (2007); *see also* note 4, *supra* (citing similar authorities).

years), and Watson still did not have FDA approval to sell generic Lidoderm. As Plaintiffs have explained,"[a]t the time Endo submitted its citizen petition and amendments concerning Lidoderm, the FDA had a well-known practice of withholding both tentative and final ANDA approval until after its consideration of and response to a citizen petition was complete." (EPP CAC ¶ 49.)

The Lidoderm Settlement provided Watson with a license to make and sell generic Lidoderm beginning on September 15, 2013, more than two years earlier than expiration of the '529 Patent, which was the latest-expiring patent covering Lidoderm. (RJN Ex. A § 2(a); DPP CAC ¶¶ 60, 94; EPP CAC ¶¶ 68, 104; GEHA FAC ¶¶ 59, 97.) The early-entry license agreed upon by the parties was subject to FDA approval of Watson's ANDA. (Ex. A § 2(i).) The license was also exclusive for the initial seven and a half months of the license term. (*Id.* § 2(a).) During this initial period, and until a second generic entered the market, Watson agreed to pay Endo a 25% royalty on sales of Watson's generic Lidoderm. (*Id.* § 3(a).)

Despite the agreement allowing Watson to sell generic Lidoderm beginning on September 15, 2013, Watson could not begin selling its generic version of Lidoderm until the FDA approved its ANDA, and it was unclear at the time of the settlement when the FDA might approve Watson's ANDA. To mitigate this uncertainty, the parties agreed that Endo would provide Lidoderm product to Watson, thereby enabling Watson to begin selling product in competition with Endo *even earlier*—beginning on January 1, 2013. (DPP CAC ¶ 95; EPP CAC ¶¶ 105-06; GEHA FAC ¶ 98.) This was more than eight months prior to the agreed-upon early-entry license, and almost three years earlier than expiration of the '529 Patent. Endo and Teikoku also agreed that they would not submit any new Citizen Petition relating to Lidoderm, and Endo agreed not to further amend its existing Citizen Petition. (Ex. A § 5(a).) The parties also agreed, in the event that final FDA approval for generic Lidoderm was delayed beyond January 1, 2014, Endo would continue to provide Lidoderm product that Watson could sell in competition with Endo, potentially until as late as September 1, 2015. (*Id.* § 3(c)-(d).) Product supplied by Endo was required under the Lidoderm Settlement to be sold only through Watson's wholesaler affiliate, Anda, and Anda was

given full discretion over pricing and other terms of sale. (*Id.* § 3(e);[7] DPP CAC ¶ 95.) The Lidoderm Settlement thus permitted Watson's wholesaler affiliate, Anda, to compete with Endo in the sale of Lidoderm starting on January 1, 2013—almost three years earlier than if it had continued to litigate the '529 Patent and lost, and without the risk of damages stemming from the patent litigations.

III. PLAINTIFFS AND CLAIMS

Plaintiffs have filed these Amended Complaints alleging that the Lidoderm Settlement is an unlawful reverse payment agreement. Four entities that allege to have directly purchased branded and/or generic Lidoderm ("Direct Purchaser Plaintiffs") filed a putative class action raising claims under the federal antitrust laws. (DPP CAC ¶¶ 153-189 (alleging five counts under Sections 1 and 2 of the Sherman Act).) Direct Purchaser Plaintiffs' Counts I and II assert that the Lidoderm Settlement was an unreasonable restraint of trade in violation of Section 1 of the Sherman Act under rule-of-reason and *per se* liability standards, respectively. Count III asserts that the Lidoderm Settlement constituted a "conspiracy to monopolize" in violation of Section 2 of the Sherman Act. And Counts IV and V, asserted against only the Brand Defendants, allege that the

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[7] Although Plaintiffs do not assert any claim of price fixing, they imply in passing that this provision could constitute an unlawful agreement on price. (DPP CAC ¶ 98; EPP CAC ¶ 109; GEHA FAC ¶ 156.) This suggestion is contrary to the clear terms of the Lidoderm Settlement. Section 3(e) provides in relevant part:

> The Brand Product supplied by Endo/Teikoku to Watson's Wholesale Affiliate . . . may be resold solely by Watson's Wholesaler Affiliate to Third Parties for use solely in the Territory *on pricing and other terms determined by Watson's Wholesaler Affiliate in its sole discretion*, provided that neither Watson nor any of its Affiliates . . . shall sell, distribute or dispose of Branded Product in any manner that would constitute a Bundled Sale. Watson agrees that its Wholesaler Affiliate will honor all Endo price-related contracts as communicated to all Endo wholesalers from time to time in the ordinary course of business, *provided that* the price related contracts do not impose any requirements on Watson's Wholesale Affiliate that would be inconsistent with requirements imposed upon other Lidoderm® wholesalers, and further provided that such price-related contracts shall not conflict with the terms of this Agreement. Watson shall comply with all Applicable Laws in connection with its resale of the Brand Product.

(RJN Ex. A § 3(e) (emphases added).) This language is clear that Anda was free to sell branded product in competition with Endo. Watson could even supply customers who had an existing contract with Endo. Anda could not, however, violate any "Applicable Laws," interfere with pricing on existing Endo contracts, or make "Bundled Sales," a defined term under Medicare regulations. (RJN Ex. A. § 1(f).)

Lidoderm Settlement resulted in monopolization or attempted monopolization, respectively, of a "relevant market." The only alleged conduct underlying all these claims by the Direct Purchaser Plaintiffs is the Defendants' settlement of the '529 and Rolf Lawsuits pursuant to the terms of the Lidoderm Settlement.

Seven employee health and welfare benefit plans, a municipal corporation, and two individual consumers (together, the "End-Payor Plaintiffs"), all of whom allege that they paid someone other than the Defendants for branded and/or generic Lidoderm, assert claims on behalf of a putative class of indirect purchasers under (1) the antitrust laws of twenty-seven states, the District of Columbia, and Puerto Rico, (2) California's Unfair Competition Law, and (3) unjust enrichment theories based on the laws of all states except Indiana and Ohio plus the District of Columbia. (EPP CAC ¶¶ 9-18, 162-205.) Government Employees Health Association ("GEHA"), allegedly another indirect purchaser, filed its own complaint that asserts claims under (1) the antitrust laws of twenty-six states, the District of Columbia, and Puerto Rico, (2) the consumer protection laws of thirty-six states and the District of Columbia, and (3) unjust enrichment theories based on the laws of all states except Indiana and Ohio plus the District of Columbia. (GEHA FAC ¶¶ 125-28.) As with the Direct Purchaser Plaintiffs' claims, each and every count asserted by the End-Payor Plaintiffs and GEHA is fundamentally based on the alleged unlawfulness of the Lidoderm Settlement.

Defendants now move to dismiss all the claims in the Amended Complaints for failure to state a claim as a matter of law. All of Plaintiffs' claims in all three Amended Complaints, whether based on federal law or state law, fail for the following reasons:

- The *per se* standard is inapplicable as a matter of law, thus the Lidoderm Settlement is not a *per se* unlawful restraint of trade under federal or state antitrust laws—*i.e.*, Count II by the Direct Purchaser Plaintiffs and certain allegations by the End-Payor Plaintiffs and GEHA (Section I of the Argument, *infra* pp. 13-15;
- The Lidoderm Settlement was not a reverse payment subject to antitrust scrutiny, and in any event was not unreasonable as a matter of law, and therefore the Lidoderm Settlement is not an unlawful restraint of trade under federal or state antitrust laws based on

the rule-of-reason standard—*i.e.*, Count I by the Direct Purchaser Plaintiffs, Count I by the End-Payor Plaintiffs, and Count IV by GEHA (Section II of the Argument, *infra* pp. 16-20); and, alternatively, the Lidoderm Settlement cannot be shown to have caused injury to Plaintiffs, which is fatal to those same counts (Section III of the Argument, *infra* pp. 21-24);

- For the same reasons set out in Sections II and III of the Argument, the Lidoderm Settlement does not constitute monopolization, a conspiracy to monopolize, or attempted monopolization under federal or state antitrust laws—*i.e.*, Counts III, IV, and V by the Direct Purchaser Plaintiffs, Count II by the End-Payor Plaintiffs, and Counts I, II, and III by GEHA; and the same counts also should be dismissed for failure to plead monopoly power by a single entity (Section IV, *infra* pp. 24-26);

- For the reasons set out in Sections II and III of the Argument, as well as for specific pleading deficiencies as to certain of the state laws as set out in Section V of the Argument (*infra* pp. 26-46), the Lidoderm Settlement did not violate state consumer protection laws—*i.e.*, Count III by the End-Payor Plaintiffs and Count V by GEHA; and

- For the same reasons set out in Sections II and III of the Argument, as well as for specific pleading deficiencies as to certain of the state laws as set out in Section V of the Argument (*infra* pp. 26-46), the Lidoderm Settlement did not result in unjust enrichment based on state laws—*i.e.*, Count IV by the End-Payor Plaintiffs and Count VI by GEHA.

ARGUMENT

Antitrust complaints that fail to state a claim that is "plausible on its face" must be dismissed. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558-59, 570 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) ("[O]nly a complaint that states a plausible claim for relief survives a motion to dismiss."). "Naked assertion[s]," "[t]hreadbare recitals of the elements of a cause of action," and "mere conclusory statements" are insufficient to survive dismissal. *Id*. at 678 (citation omitted). As the Ninth Circuit warned in *Kendall v. Visa U.S.A., Inc.*, "discovery in antitrust cases frequently causes substantial expenditures and gives the plaintiff the opportunity to extort large settlements even where he does not have much of a case." 518 F.3d 1042, 1047 (9th Cir. 2008). Consequently, courts should scrutinize claims "at the point of minimum expenditure of

time and money by the parties and the court." *Twombly*, 550 U.S. at 558 (internal quotation marks and citation omitted).

Plaintiffs' allegations do not plausibly allege an antitrust violation. *Actavis* defined the standard for evaluating patent settlements that allegedly involve reverse payments. The Supreme Court not only explicitly rejected a "*per se*" standard for such settlements, *Actavis*, 133 S. Ct. at 2234, it also made clear that even where "large and unjustified" reverse payments are involved, patent settlements must be evaluated under the rule of reason, and only "sometimes" may be found unlawful. *Id.* at 2232. A party challenging a so-called reverse payment "must prove its case as in other rule-of-reason cases," and liability will attach only if plaintiffs meet their burden of proving "the presence of significant unjustified anticompetitive consequences." *Id.* at 2237-38.

Critically, however, antitrust scrutiny is appropriate only where there actually is a "reverse payment." *See id.* Where there is no reverse payment, the inquiry ends and no rule of reason analysis is required. *Id.*; *see also In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12–cv–995(WHW), 2014 WL 282755, at *7 (D.N.J. Jan. 24, 2014) ("Finding that a settlement contains a reverse payment is a necessary prerequisite to undertaking the broader *Actavis* rule of reason analysis."), *appeal pending*, No. 14-1243 (3d Cir. appeal docketed Jan. 30, 2014). *Actavis* explicitly sanctioned settlements in which the parties compromise on an entry date before patent expiry: "[Pharmaceutical manufacturers] may, as in other industries, settle . . . by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Actavis*, 133 S. Ct. at 2237.[8]

IV. PLAINTIFFS HAVE FAILED TO STATE A *PER SE* CLAIM

Plaintiffs claim that the term in the Lidoderm Settlement by which Watson's license to make generic Lidoderm could be exclusive for up to seven and a half months constituted a "market

[8] *Actavis* was an action pursuant to Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. *Id.* at 2230. As the Court acknowledged, "Section 5 'encompass[es] . . . practices that violate the Sherman Act and the other antitrust laws.'" *Id.* (quoting *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 454 (1986) (alteration in original)). Although claims alleging violations of Sections 1 and 2 of the Sherman Act, claims arising under state antitrust and consumer protection statutes, and common law unjust enrichment claims may face various additional hurdles, some of which are addressed below, *Actavis'* multi-step framework for analyzing reverse payment settlements applies to each of Plaintiffs' various claims, all of which sound in antitrust.

allocation" agreement between the parties that is a *per se* violation of the antitrust laws. (DPP CAC ¶¶ 160-67; EPP CAC ¶ 123; GEHA FAC ¶ 156 (also alleging that Lidoderm Settlement is a *per se* unlawful price-fixing agreement).) Plaintiffs are wrong as a matter of law. The Supreme Court in *Actavis* firmly rejected the suggestion that Hatch-Waxman litigation settlements could be presumptively unlawful, or even subject to the "quick look" standard, under which settlements presumptively would be unlawful if they involved alleged payments by the brand to the settling generic. *See Actavis*, 133 S. Ct. at 2237.

Courts have adopted the *per se* standard only in situations where the conduct can safely be presumed to be unlawful because it is unreasonably anticompetitive every time it arises. *See Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 19-20 (1979). Of course, a patent by its very nature restricts competition, and so a patent litigation settlement in which the alleged infringer acknowledges the patent's validity could be characterized as having the same anticompetitive tendencies as the patent at issue. *See Actavis*, 133 S. Ct. at 2239 (Roberts, C.J., dissenting) ("Like most litigation, patent litigation is settled all the time, and such settlements—which can include agreements that clearly violate antitrust law, such as licenses that fix prices, or agreements among competitors to divide territory—do not ordinarily subject the litigants to antitrust liability."). But courts "have long recognized that the settlement of patent litigation does not by itself violate the antitrust laws." *Id.* (Roberts, C.J., dissenting). As one court has explained, "a rule that too quickly condemns [Hatch-Waxman litigation settlements] as *per se* illegal, potentially chilling efforts to research and develop new drugs and challenge the patents on brand-name drugs, does competition—and thus, the Sherman Act—a disservice." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003). At bottom, a *per se* standard would improperly deprive the Brand Defendants of patent rights by unlawfully assuming that their patents are invalid and it would have an unnecessarily chilling effect on patent settlements. *See generally id.* at 257. *Actavis* forbids, as a matter of law, Plaintiffs' attempt to shoehorn the Defendants' Hatch-Waxman litigation settlement into the limited categories of conduct deemed *per se* unlawful under the antitrust laws.

Nor does the challenged exclusivity otherwise give rise to a claim under the antitrust laws.

Indeed, the law explicitly *permits* patent holders to grant exclusive licenses such as the license in the Lidoderm Settlement. *See* 35 U.S.C. § 261 ("The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States."); *Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 23 (1964) ("[P]atent rights have long included licenses 'to make, use and vend' the patented article 'for any royalty, or upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure.'" (citation omitted)); *United States v. Gen. Elec. Co.*, 272 U.S. 476, 489 (1926) ("The owner of a patent may assign it to another and convey (1) the exclusive right to make, use and vend the invention throughout the United States; or (2) an undivided part or share of that exclusive right; or (3) the exclusive right under the patent within and through a specific part of the United States.").[9]

As is the case with the limited exclusive license that was part of the Lidoderm Settlement, exclusive licenses can be perfectly compatible with the procompetitive goals of the antitrust laws. Far from supporting a *per se* antitrust violation, it is widely recognized that exclusive licenses offer procompetitive benefits. *See, e.g., Ralph C. Wilson Indus., Inc. v. Am. Broad. Companies, Inc.*, 598 F. Supp. 694, 706 (N.D. Cal. 1984) (granting summary judgment for defendants on Section 1 claim and explaining competitive benefits of exclusive licensing in television programming), *aff'd sub nom. Ralph C. Wilson Indus., Inc. v. Chronicle Broad. Co.*, 794 F.2d 1359 (9th Cir. 1986); *see also Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 311-12 (2d Cir. 2008) (recognizing that exclusive license for baseball club's intellectual property produced procompetitive benefits).

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[9] *See also United States v. Westinghouse Elec. Corp.*, 648 F.2d 642, 647 (9th Cir. 1981) ("The right to license [a] patent, exclusively or otherwise, or to refuse to license at all, is 'the untrammeled right of the patentee.'" (citation omitted)); *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 949 (Fed. Cir. 1993) (observing that "the grant of an exclusive license is a lawful incident of the right to exclude provided by the Patent Act" and affirming dismissal of Section 1 claim against license), *abrogated on other grounds by Wilton v. Seven Falls Co.*, 515 U.S. 277 (1995); III Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 707a (3d ed. 2008) ("The patent laws encourage the licensing of patents and make no exception for exclusive licensees or licensees who happen to be monopolists.").

V. ALL PLAINTIFFS' CLAIMS SHOULD BE DISMISSED BECAUSE DEFENDANTS' CONDUCT WAS NOT ANTICOMPETITIVE

A. The Lidoderm Settlement Is Not a "Reverse Payment" Under *Actavis*

Actavis established that the only settlements subject to rule-of-reason review are those involving a large and unjustified payment from the innovator to the alleged infringer in return for the infringer's promise not to introduce its product until an agreed-upon date. *Actavis*, 133 S. Ct. at 2237 (majority opinion). The Lidoderm Settlement involves no payments at all. Instead, Endo, Teikoku, and Watson settled based on a negotiated early-entry date that allowed Watson to sell Lidoderm more than two years before the '529 Patent expired, precisely the kind of settlement that the Supreme Court held is not subject to antitrust scrutiny. *See id.*

Actavis makes clear that antitrust scrutiny of reverse payment settlements is warranted only when the patent holder is paying a generic challenger "to stay[] out" of the market before the patent expires. *Id.* at 2234. Conversely, as the Supreme Court emphasized, settlements permitting a generic challenger to enter before the patent expires "bring about competition . . . to the consumer's benefit." *Id.* This is true, even though a settlement allowing the generic to enter before the patent expires itself conveys value—in many cases significant value—to the generic challenger. *See generally Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) ("*[A]ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." (emphasis in original)), *dismissed by* 104 F. App'x 178 (Fed. Cir. 2004). The key difference between an early-entry settlement and a reverse payment is that, with the former, the value to the generic comes from its sales of a competing product, and the competition benefits consumers. In contrast, where a patent holder pays the generic to refrain from competing, the payment to the generic is made whether or not the generic challenger sells the product in competition with the brand before the patent expires.

Plaintiffs focus on two settlement terms that they allege are "payments" to Watson: (1) the provision of Lidoderm product to Watson beginning on January 1, 2013; and (2) the exclusive

nature of Watson's early-entry license, which was limited to the first seven and a half months of the license term. Neither of these qualifies as a reverse payment within the meaning of *Actavis*.

1. The Provision of Lidoderm Is Not a Reverse Payment Under *Actavis*

The Lidoderm Settlement is precisely the opposite of a settlement in which the generic receives a payment to "stay out" of the market. Instead, Watson obtained the right to sell competing Lidoderm product almost three years prior to patent expiry, even though (1) Watson's ANDA had not been approved, (2) the Citizen Petition was still pending, and (3) the merits of two separate patent litigations remained unresolved. In the absence of FDA approval, and given significant uncertainty regarding whether and when Watson would receive such approval, provision of product was the only assured means of early entry. And unlike the situation where a patent holder pays the generic challenger to "stay out" of the market, the only way Watson could derive value from the product it received under the Lidoderm Settlement *was to sell it in competition with Endo*. *See Asahi Glass*, 289 F. Supp. 2d at 994 (explaining that a settlement in which the brand company agreed to supply free product to the generic and permit early generic entry under certain circumstances does not qualify as a "reverse payment" agreement because "the 'payment' in the form of free paroxetine occurred as a byproduct of increased competition, that is, of [the generic's] selling in competition with [the brand company]"). The provision of product from Endo to Watson—requiring competition to customers' benefit in order for Watson to obtain any value—distinguishes the Lidoderm Settlement from a reverse payment that requires rule-of-reason scrutiny. *See Actavis* 133 S. Ct. at 2227 (describing a "reverse payment" settlement as one where the parties agree "(1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to *pay B many millions of dollars*" (emphasis added)); *id.* at 2233 ("reverse payment settlements—*e.g.*, in which A, the plaintiff, *pays money* to defendant B" (emphasis added)).[10] Accordingly, the provision of

[10] Indeed, in *Lamictal*, the court interpreted *Actavis* as requiring a cash payment in order to satisfy the preliminary "reverse payment" hurdle. *In re Lamictal*, 2014 WL 282755, at *7-9 (granting motion to dismiss where alleged reverse payment did not involve monetary compensation). The provision of product obviously is not a cash payment and on this basis alone survives antitrust scrutiny.

Lidoderm from Endo to Watson does not satisfy the threshold requirement set forth in *Actavis*.

2. The Partially Exclusive License Is Not a Reverse Payment Under *Actavis*

Nor can Plaintiffs engineer a "reverse payment" from the terms of the early-entry license itself. Plaintiffs assert that because the license is exclusive—in that Endo agreed not to introduce or license a competing generic during the initial term of the agreement—Watson received "value" that should qualify as a reverse payment. (DPP CAC ¶ 102; EPP CAC ¶ 113; GEHA FAC ¶ 105.) But again, in clear contrast with the types of payments discussed in *Actavis*, Watson earned *nothing* unless it sold the product in competition with Endo prior to patent expiry. Nothing in the Supreme Court's endorsement of early-entry settlement agreements restricts the parties from making the early-entry license exclusive, *see Actavis*, 133 S. Ct. at 2232 (recognizing that "the Court permitted a single patentee to grant to a single licensee a license containing a minimum resale price requirement"), or gives any indication that the Supreme Court intended to overturn the well-established rule that "the grant of an exclusive license is a lawful incident of the right to exclude provided by the Patent Act." *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 949 (Fed. Cir. 1993); *see also In re Lamictal*, 2014 WL 282755, at *7-9 (rejecting as a matter of law the notion that an exclusive license could constitute a "reverse payment"). To the contrary, the Supreme Court in *Actavis* reiterated that patentees have the right to license their patents, and distinguished "reverse payments" from "traditional settlement forms." *Actavis*, 133 S. Ct. at 2232-33 (citing *United States v. Gen. Elec. Co.*, 272 U.S. 476 (1926) and *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163 (1931)).

In short, neither the provision of Lidoderm product, nor the exclusivity of Watson's license, qualify as reverse payments that are subject to the rule of reason under *Actavis*, and the Court should dismiss Plaintiffs' claims without further analysis.

B. The Lidoderm Settlement Was Reasonable as a Matter of Law

Plaintiffs have also failed to meet their burden of plausibly alleging "the presence of significant unjustified anticompetitive consequences" as required under the rule-of-reason analysis set forth in *Actavis*. 133 S. Ct. at 2238. An agreement's reasonableness must be judged as of the time it was entered into, rather than in hindsight after contingencies and unknowns have played out.

See, e.g., Polk Bros., Inc. v. Forest City Enters., Inc., 776 F.2d 185, 189 (7th Cir. 1985) (explaining that "the aftermath is the wrong focus"); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 204 (2d Cir. 2006) (noting that "the relevant time" for "assessing the behavior of the defendants" is the time at which they entered into the challenged "reverse payment" patent settlement), *abrogated on other grounds by FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013); *U.S. Philips Corp. v. Int'l Trade Comm'n*, 424 F.3d 1179, 1198 (Fed. Cir. 2005) ("To hold that a licensing agreement that satisfied the rule of reason when executed became unreasonable at some later point because of technological development would introduce substantial uncertainty into the market and displace settled commercial arrangements in favor of uncertainty that could only be resolved through expensive litigation.").

Plaintiffs have not plausibly alleged that the Lidoderm Settlement had unjustified anticompetitive consequences, or any anticompetitive consequences at all. Instead, Plaintiffs summarily assert that Watson would have begun selling generic Lidoderm earlier in the absence of the Lidoderm Settlement, and that "one or more" generic Lidoderm products would have been available "well before" Watson actually entered (DPP CAC ¶ 142; EPP CAC ¶ 147; GEHA FAC ¶ 2), irrespective of the regulatory obstacles and litigation risk that would need to be overcome to achieve this result. Plaintiffs' entire argument is tantamount to a preference for a different settlement, one that provided for even earlier entry by multiple licensees. But as the Supreme Court has made clear, courts cannot condemn an otherwise procompetitive agreement "whenever some other approach might yield greater competition." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004).

The Lidoderm Settlement was not merely reasonable in light of all relevant circumstances as they existed when it was executed on May 28, 2012—it was *procompetitive*. *First*, at the time of the settlement, the '529 Patent was not due to expire until October 27, 2015. (DPP CAC ¶ 60; EPP CAC ¶ 68; GEHA FAC ¶ 6.) Three other patents covering Lidoderm (at issue in the Rolf Lawsuit against Watson) were not due to expire until March 30, 2014. (DPP CAC ¶ 70; EPP CAC ¶ 76; GEHA FAC ¶ 69.) The Lidoderm Settlement enabled Watson to market Lidoderm in competition with Endo beginning on January 1, 2013, almost three years before Endo's patents

otherwise would have allowed.

Second, the '529 Lawsuit and Rolf Lawsuit were both still pending in the district courts at the time of the settlement on May 28, 2012. Although the '529 Lawsuit had proceeded to trial, no decision had been rendered. And the Rolf Lawsuit was still in its infancy. Entry on January 1, 2013 was far earlier than Watson could have achieved had it attempted to secure favorable rulings in both litigations—even if only at the district court, let alone on appeal.

Third, at the time of the settlement, the FDA had not yet approved Watson's ANDA, and it was unclear when the FDA might do so given that a Citizen Petition had been pending for nearly *six years*. There is no dispute that the FDA would not grant final approval "until after its consideration of and response to a citizen petition was complete." (EPP CAC ¶ 49.) And most importantly, the Lidoderm Settlement ensured a second source of Lidoderm in competition with Endo nearly three years before patent expiry, unimpeded by the Brand Defendants' patent rights or the absence of FDA approval, either of which was an independent bar to Watson's entry at the time of the settlement.

In considering the viability of Plaintiffs' claims, the court should not give credence to implausible allegations or naked assertions of law bereft of any factual support. *See, e.g.*, *Twombly*, 550 U.S. at 569 (articulating the plausibility standard for pleading, and concluding that "antitrust conspiracy was not suggested by the facts adduced under either theory of the complaint, which thus fails to state a valid § 1 claim"); *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 ("The court need not, however, accept as true allegations that contradict matters properly subject to judicial notice or by exhibit. . . . Nor is the court required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences."), *opinion amended on denial of reh'g*, 275 F.3d 1187 (9th Cir. 2001). Any allegations by Plaintiffs that the Lidoderm Settlement was anticompetitive, (*e.g.*, DPP CAC ¶ 120, EPP CAC ¶; GEHA FAC ¶ 111-12), are conclusory and implausible and thus fail to satisfy Plaintiffs' pleading burden as a matter of law.

VI. PLAINTIFFS HAVE FAILED TO PLAUSIBLY ALLEGE THAT THE LIDODERM SETTLEMENT CAUSED INJURY

Plaintiffs' claims also fail because they cannot plausibly allege any injury caused by the Lidoderm Settlement. On this basis alone, all claims against Endo, Teikoku, and Watson should be dismissed for lack of standing.

Private antitrust plaintiffs must demonstrate standing, and when a complaint fails by its terms to establish standing, it must be dismissed. *See, e.g.*, *Parks v. Watson*, 716 F.2d 646, 658 (9th Cir. 1983) ("'The plaintiff's claim may be dismissed for lack of standing as a matter of law where there is an insufficient showing of causation.'" (internal citation omitted) (quoting *Solinger v. A & M Records, Inc.*, 586 F.2d 1304, 1309 (9th Cir.1978)).

Injury-in-fact, one indispensable component of standing, cannot be based on undue speculation. *See Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 543 (1983) (noting that "nothing but speculation informs the Union's claim of injury by reason of the alleged unlawful coercion" and explaining that, in evaluating a private antitrust claim, "it is appropriate . . . 'to consider whether a claim rests at bottom on some abstract conception or speculative measure of harm'" (citation omitted)); *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 267 (3d Cir. 1998) ("appellants cannot foist their version of what might have been on the court under the rubric of antitrust injury"); *City of San Jose v. Office of Comm'r of Baseball*, No. C-13-02787 RMW, 2013 WL 5609346, at *11 (N.D. Cal. Oct. 11, 2013) (granting motion to dismiss because plaintiff "lacks standing to assert an antitrust claim" where the alleged injury "depends on an assumption that future events will take place, including . . . obtain[ing] financing, regulatory approvals"); *In re Napster, Inc. Copyright Litig.*, 354 F. Supp. 2d 1113, 1124 (N.D. Cal. 2005) ("Simply put, the antitrust laws are not intended to provide a remedy for such speculative assertions of injury.").

Plaintiffs' claims of injury depend on allegations that, but for the Lidoderm Settlement, "Watson would have entered the market" upon FDA approval on August 23, 2012, "or shortly after that date." (DPP CAC ¶ 142; EPP CAC ¶ 147; *see also* GEHA FAC ¶ 2.) Their claims therefore are premised on the speculation that Watson would have received FDA approval of its ANDA on

August 23, 2012, *and* that Watson would have prevailed in the '529 Lawsuit and Rolf Lawsuit (or that Watson would have launched "at risk" of patent damages for infringement).

Plaintiffs simply assume that if the parties had not entered into the Lidoderm Settlement the FDA still would have approved Watson's ANDA on August 23, 2012. Yet it is far from clear that, absent the Lidoderm Settlement, the FDA would have resolved Endo's Citizen Petition—and simultaneously approved Watson's ANDA—as quickly as August 23, 2012. Even if Plaintiffs could show that, absent the Lidoderm Settlement, the FDA would have approved Watson's ANDA on August 23, 2012, their injury claims are still too speculative to survive because they assume that Watson either would have prevailed (through appeal) in both the '529 and Rolf Lawsuits, or would have launched at risk upon receipt of FDA approval. FDA approval does not shield a generic from liability for patent infringement. Absent the Lidoderm Settlement, sales by Watson of generic Lidoderm before October 17, 2015, would have been at risk of treble damages for infringing the Brand Defendants' patents unless and until Watson prevailed (including through any appeals) in *both* the '529 and Rolf Lawsuits. It is implausible to assume that both litigations would have been finally resolved by August 23, 2012. *See, e.g.*, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d at 200 ("a legal theory dependent on predicting the outcome of a specific lawsuit is unduly speculative" (citing *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990))); *see also Volvo N. Am. Corp. v. Men's Int'l Prof'l Tennis Council*, 857 F.2d 55, 63 (2d Cir. 1988) (dismissing antitrust claims concerning "'contingent future events that may not occur as anticipated, or indeed may not occur at all'" (citation omitted)); *Asahi Glass*, 289 F. Supp. 2d at 993 ("No one can be *certain* that he will prevail in a patent suit." (emphasis in original)). The appeals process for any decision in the '529 Lawsuit (which went to trial in March 2012 and was still undecided as of May 2012) would certainly have stretched well past August 23, 2012. And Plaintiffs themselves concede that the Rolf Lawsuit had only "barely proceeded past the pleading stage" and thus certainly would not have been fully and finally resolved by August 23, 2012. (DPP CAC ¶ 89; EPP CAC ¶ 96; GEHA FAC ¶ 89.)

To the extent that Plaintiffs allege that Watson would have launched "at risk" upon FDA approval of Watson's generic Lidoderm product, without waiting for resolution of the patent cases

and thereby exposing itself to a potentially catastrophic risk of treble damages based on a product whose revenues were nearly $1 billion, (DPP CAC ¶ 3), their claims are speculative and implausible. Plaintiffs do not suggest any reason why Watson would incur such a large and unnecessary risk, and make no allegation that Watson had a history of launching at risk under similar circumstances. While Plaintiffs point to statements Watson made to Wall Street analysts in late 2011 and early 2012, (DPP CAC ¶ 124; EPP CAC ¶ 125), those statements actually indicate just the opposite: that Watson would not have launched at risk. For example, in its earnings call for the first quarter of 2012, Watson made clear that it did not expect ANDA approval until the Citizen Petition was resolved, and also that it was not going to launch at risk. Watson explained that, although it had increased capacity and procured raw materials to be in a position to launch generic Lidoderm, an actual launch was contingent on FDA approval, over which "there is still the Citizen Petition overhang, which sits out there and of course, we're waiting for a trial decision. But we are doing everything we can to be ready to go at the earliest possible time." (RJN Ex. D, Q1 2012 Earnings Call Transcript.)[11]

In these circumstances, Plaintiffs' assertion that launch would have occurred prior to the final resolution of the two lawsuits is simply too speculative to permit the claim to go forward. *See In re Ciprofloxacin*, 261 F. Supp. 2d at 204 (concluding that a claim based on the premise that a generic company would have launched at risk was too speculative to "withstand a motion to dismiss"); *see also, e.g.*, 130 Cong. Rec. H9115 (daily ed. Sept. 6, 1984) (statement of Rep. Waxman) ("The facts of life are that a generic drug manufacturer will await, as a practical matter, until the decision of a court on a patent challenge before that manufacturer markets a generic

[11] The Court should consider the full contents of Watson's earnings call transcript, which is quoted in two of the Amended Complaints (DPP CAC ¶ 124; EPP CAC ¶ 125), on the ground that it is incorporated by reference into the Amended Complaints. *See, e.g.*, *Barnes*, 2013 WL 4426244 at *3. The earnings call transcript also qualifies for judicial notice because it is "not subject to reasonable dispute because it . . . can be accurately and readily determined form sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b); *Rosenbaum Capital, LLC v. McNulty*, 549 F. Supp. 2d 1185, 1189 (N.D. Cal. 2008) (taking judicial notice of earnings call transcript, which was not referenced in the plaintiff's complaint, because it "is publicly available and was disclosed to the market").

drug.").

Because Plaintiffs' injury allegations are based entirely on speculation, they must be dismissed. *See, e.g.*, *Twombly*, 550 U.S. at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level.").

VII. PLAINTIFFS' ALLEGATIONS THAT ENDO AND TEIKOKU *SHARED* MONOPOLY POWER IN THE RELEVANT MARKET ARE FATAL TO THEIR MONOPOLIZATION CLAIMS

Plaintiffs' claims of monopolization and attempted monopolization depend on the underlying allegations of an unlawful reverse payment settlement and therefore they fail as a matter of law for the reasons discussed in Sections II and III, *supra*: (1) the Lidoderm Settlement does not qualify as a potentially unlawful reverse payment agreement under *Actavis*; (2) even if the Lidoderm Settlement did qualify as a reverse payment agreement, it would not be unlawful because, as a matter of law, it was not unreasonable; and (3) plaintiffs do not plausibly allege that the settlement caused injury.

Plaintiffs' claims of monopolization and attempted monopolization also fail as a matter of law because each requires pleading monopolization by a *single* entity. *See Sun Dun, Inc. of Wash. v. Coca-Cola Co.*, 740 F. Supp. 381, 391 (D. Md. 1990) ("An examination of the history of the Sherman Act reveals that Congress' concept of 'monopoly' did not include 'shared monopolies' or 'oligopolies' at all, but rather the complete domination of a market by a *single* economic entity."). "[A] §2 claim can only accuse one firm of being a monopolist." *Midwest Gas Servs., Inc. v. Ind. Gas Co.*, 317 F.3d 703, 713 (7th Cir. 2003). As the Ninth Circuit has stated, "[t]o pose a threat of monopolization, one firm *alone* must have the power to control market output and exclude competition." *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1443 (9th Cir. 1995).

The Amended Complaints plead only a shared monopoly by both Endo and Teikoku: "Endo/Teikoku possessed substantial market power (*i.e.*, monopoly power) in the relevant market." (DPP CAC, ¶ 179; EPP CAC ¶ 173; GEHA FAC ¶¶ 126, 142.) There are no claims in the Amended Complaints that either Endo or Teikoku individually possesses, or is in danger of possessing, monopoly power. While the Amended Complaints acknowledge that Endo, Teikoku Seiyaku, and Teikoku Pharma are separate entities, that "Endo markets and sells Lidoderm

throughout the United States," and that "Teikoku Seiyaku manufactures Lidoderm in Japan for commercial sale in the United States by Endo under a Manufacturing and Supply Agreement with Endo," (DPP CAC ¶¶ 13-15; EPP CAC ¶ 19-21; *see also* GEHA FAC ¶ 23-25), they nonetheless proceed to plead that Endo and Teikoku had a shared monopoly over lidocaine patch 5% in the U.S. market. (DPP CAC ¶¶ 130-41; EPP CAC ¶¶ 173-77; GEHA FAC ¶ 126, 127, 130, 134, 137, 142, 143, 145-47, 149.) Each of Counts III – V of the DPP CAC, Count II of the EPP CAC, and Counts II and III of the GEHA FAC is based on allegations of shared monopoly power between Endo and Teikoku.

Plaintiffs in *In re Wellbutrin XL Antitrust Litigation*, No. 08-2431, 2009 WL 678631, at *6-8 (E.D. Pa. Mar. 13, 2009), like Plaintiffs here, pled a shared monopoly involving the producers and distributors of the drug Wellbutrin XL. The *Wellbutrin* court rejected plaintiffs' argument that Biovail (the producer) and GlaxoSmithKline (the distributor) operated as a "single economic entity" because they had "a close relationship designed to bring a single product to market." *Id.* at *7. The court found that "GSK is a licensee of Biovail rather than a joint venturer," and "Biovail profited as a recipient of royalties on GSK's profits from sales of Wellbutrin, but did not participate in the U.S. market directly." *Id.* at *7-8. The court dismissed the Section 2 monopolization claim against Biovail but not GSK because the "gist of th[e] complaint [was] that GSK had a monopoly" on the sale of Wellbutrin. *Id.* at *8. Here, as in *Wellbutrin*, the Amended Complaints allege that Teikoku only received royalties from Endo and that it did not participate in the U.S. market (DPP CAC, ¶¶ 14-15; EPP CAC ¶ 20-21); however, unlike in *Wellbutrin*, the "gist of the complaint" is not that Endo alone had monopoly power. Indeed, there are no counts in the Amended Complaints that allege that Endo had a monopoly in the U.S. market for lidocaine patch 5%. Therefore, the Section 2 monopolization claims must be dismissed against both Endo and Teikoku. *Id.*; *see also Sun Dun*, 740 F. Supp. at 390 (dismissing Section 2 monopolization claim because "[n]owhere does plaintiff allege the requisite market power on the part of any *individual* defendant").

The "shared monopoly" allegations likewise doom Plaintiffs' attempted monopolization claims. *See, e.g., Standfacts Credit Servs., Inc. v. Experian Info. Solutions, Inc.*, 405 F. Supp. 2d

1141, 1152 (C.D. Cal. 2005) (finding that "because Plaintiffs have not alleged . . . that any single Defendant will achieve monopoly power in the retail market, the Court finds that Plaintiffs have failed to state a claim for attempted monopolization under section 2 of the Sherman Act"), *aff'd in part*, 294 F. App'x 271 (9th Cir. 2008). And Plaintiffs' "allegation of conspiracy to create a shared monopoly does not plead a claim of conspiracy under section 2." *Id.*; *see also Int'l Longshore and Warehouse Union v. ICTSI Oregon, Inc.*, No. 3:12-cv-01058-SI, 2014 WL 1218116, at *11 (D. Or. Mar. 24, 2014) ("allegations of [] a conspiracy to create a 'shared monopoly' fail to state a claim under Section 2"); *Sun Dun*, 740 F. Supp. 2d at 392 ("When . . . two or more competitors conspire to create a market environment in which competition and market entry is improperly restricted, but which market power continues to be shared among these otherwise unrelated entities, this Court holds that there is no conspiracy to monopolize claim stated under Section 2, and the claim must therefore be *dismissed*." (emphasis in original)).

VIII. VARIOUS STATE LAW CLAIMS ALLEGED BY INDIRECT PURCHASERS MUST BE DISMISSED

The allegations concerning Defendants' conduct in the End-Payor Plaintiffs' Consolidated Amended Complaint and Government Employee Health Association's First Amended Complaint are virtually identical to those found in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint. But because they did not purchase Lidoderm or generic Lidoderm directly from the Defendants, End-Payor Plaintiffs and GEHA are barred from seeking damages under federal antitrust laws. *See Illinois Brick v. Illinois*, 431 U.S. 720, 735 (1977). In an effort to circumvent this prohibition, End-Payor Plaintiffs and GEHA assert more than 100 state statutory and common law claims based on allegations that they indirectly purchased, paid, or provided reimbursement for Lidoderm and/or generic Lidoderm.[12]

Plaintiffs' reliance on state laws do not save their complaints from dismissal. As a threshold matter, Plaintiffs' state law claims fail for the same reasons that the federal law claims

[12] For a summary of claims alleged by End-Payor Plaintiffs, see Appendix 2. For a summary of claims alleged by GEHA, see Appendix 3.

fall short.[13] Yet even if the Court were to allow the Direct Purchaser Plaintiffs to proceed to discovery, nearly all of End-Payor Plaintiffs' claims must be dismissed for lack of standing, for failure to state a claim, or for other state-specific reasons. GEHA's complaint must be dismissed in its entirety—it lacks Article III standing to bring claims under the laws of any state other than Missouri, and its Missouri-based claims must be dismissed for reasons set forth below.[14]

A. Plaintiffs Lack Article III Standing to Bring Claims Under the Antitrust, Consumer Protection, and Unjust Enrichment Laws of the States[15] Where They Have Not Suffered Injury

While End-Payor Plaintiffs and GEHA each purport to bring claims under the common law and statutes of fifty states, their complaints lack factual allegations to support standing to bring claims under the laws of many jurisdictions. At most, each Plaintiff has standing to bring a claim only under the laws of the state in which its business sits or where he or she resides. Accordingly, claims under fifty state laws must be trimmed to eight for End-Payor Plaintiffs and one for GEHA.

Whether plaintiffs have standing to bring each of their claims is "the threshold question in every federal case." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). If Plaintiffs do not have Article III standing to bring a claim, the Court lacks the power to hear that claim. *Id.* To demonstrate constitutional standing, Plaintiffs must establish: "(1) an injury in fact; (2) traceability, *i.e.*, a causal connection between the injury and the actions complained of; and (3) redressability." *Easter v. Am. W. Fin.*, 381 F.3d 948, 961 (9th Cir. 2004) (citing *Lujan v. Defenders of Wildlife*, 504

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[13] *See In re Graphics Processing Units Antitrust Litig.* (*GPU I*), 527 F. Supp. 2d 1011, 1025 (N.D. Cal. 2007) ("Since plaintiffs' federal and state-law antitrust claims are predicated on the same allegations" and since plaintiffs failed to state a claim under federal law, those allegations "likewise are insufficient to state a claim" under state law); *see also In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1382 (N.D. Ga. 2010) ("Because the Plaintiffs' allegations do not state a plausible antitrust claim under federal law, the Indirect Purchasers also do not state a plausible antitrust claim under state law"); *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 139 (E.D.N.Y. 2003) ("[S]ince Plaintiffs fail to state a claim under the Sherman Act, and since the state antitrust law claims are based on the same allegations, those claims are also dismissed."), *aff'd*, 466 F.3d 187 (2d Cir. 2006), *abrogated on other grounds by FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

[14] For a summary of grounds for dismissal of claims alleged by End-Payor Plaintiffs and GEHA, see Appendix 1.

[15] Defendants throughout this brief use the term "states" to collectively refer to the separate jurisdictions at issue, including states, commonwealths, the District of Columbia, and Puerto Rico.

U.S. 555, 560-61 (1992)).

When faced with a motion to dismiss that challenges a claimant's standing, "the party invoking federal jurisdiction bears the burden of establishing these elements." *See Lujan*, 504 U.S. at 561. If a complaint "on its face fails to allege facts sufficient to establish subject matter jurisdiction," the court must dismiss the complaint. *In re Dynamic Random Access Memory (DRAM) Antitrust Litig.*, 546 F.3d 981, 984-85 (9th Cir. 2008).

Because "[a] plaintiff's standing to sue must be analyzed on the basis of *each* claim asserted," courts must evaluate each state law claim and determine whether plaintiffs have suffered injury in that state. *In re Wellbutrin XL Antitrust Litig.* (*Wellbutrin XL*), 260 F.R.D. 143, 151, 152 (E.D. Pa. 2009) (emphasis added). District courts addressing similarly overbroad claims have found no standing to bring claims under state laws where named plaintiffs did not allege that they suffered an injury in that particular state. *See In re Ditropan XL Antitrust Litig.* (*Ditropan XL*), 529 F. Supp. 2d 1098, 1107 (N.D. Cal. 2007) (observing that "[p]laintiffs bear the burden of demonstrating standing," and concluding that the plaintiffs had not carried that burden in states where they neither resided nor personally purchased Ditropan XL, and "dismiss[ing] for lack of standing the claims based on the antitrust law of . . . twenty-four states"); *GPU I*, 527 F. Supp. 2d at 1026-27 (dismissing indirect purchasers' claims in states where none of the named plaintiffs resided); *see also Wellbutrin XL*, 260 F.R.D. at 157 (dismissing state law claims in every state in which no named plaintiff resided or purchased Wellbutrin XL).[16]

[16] End-Payors Plaintiffs' class action allegations do not save their overbroad claims. The fact that their complaint alleges that they intend to represent a class "adds nothing to the question of standing, for even named plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent." *Lewis v. Casey*, 518 U.S. 343, 357 (1996) (citations and internal quotation marks omitted). Although some district courts have deferred the question of standing until class certification, citing *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999), the Ninth Circuit has rejected that approach. The Ninth Circuit explained in *Easter* that "*Fibreboard* does not require courts to consider class certification before standing." *Easter*, 381 F.3d at 962. Rather, except in a narrow set of circumstances, district courts should "address[] the issue of standing before [they] address[] the issue of class certification." *Id*; *see GPU I*, 527 F. Supp. 2d at 1026-27 (recognizing that, "[t]he Ninth Circuit . . . has held that standing can be addressed before class certification, where . . . the court is not considering a global class settlement" and granting defendants' motion to dismiss claims under state laws where plaintiffs did *(cont'd)*

1. End-Payor Plaintiffs Do Not Have Standing to Bring Claims Under the Laws of States Where They Do Not Reside or Have a Principal Place of Business

End-Payor Plaintiffs assert claims under the laws of fifty states. (EPP CAC ¶ 201.) But End-Payor Plaintiffs reside in or have places of business in only eight states,[17] and End-Payor Plaintiffs only have standing to pursue claims arising under the laws of those eight states.

End-Payor Plaintiffs' vague allegations that they "indirectly purchased, paid and/or provided reimbursement for Lidoderm and/or the generic version of Lidoderm once it became available, other than for resale," in twenty-two states where they do not have a principal place of business do not confer standing on Plaintiffs to bring claims under those states' laws.[18] (EPP CAC ¶¶ 9-16.) The mere allegation that Plaintiffs' members were dispensed the product in a particular state is not sufficient to confer standing on the Plaintiffs.[19] Courts addressing whether health plans have standing to bring suit under the laws of any state other than where their principal place of business is located have required far more detailed allegations that show that the plans were parties to the transactions in those states.[20]

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not reside)); *Ditropan XL*, 529 F. Supp. 2d at 1107 (rejecting Indirect Purchaser Plaintiffs' argument that "the determination of standing is premature prior to class certification," citing *Easter* and distinguishing *Fibreboard*).

[17] End-Payor Plaintiffs allege that they reside or that their principal places of business are in the following states: California, Illinois, Massachusetts, Minnesota, New York, Pennsylvania, Rhode Island, and West Virginia. (EPP CAC ¶¶ 9-18.)

[18] End-Payor Plaintiffs allege that they indirectly purchased, paid and/or provided reimbursement for lidocaine patch 5% in the following states where they do not otherwise have a principal place of business: Alabama, Arizona, Arkansas, Colorado, Connecticut, Delaware, Florida, Georgia, Kansas, Kentucky, Maine, Missouri, Nevada, New Hampshire, New Jersey, North Carolina, North Dakota, South Carolina, South Dakota, Tennessee, Texas, and Wisconsin. (EPP CAC ¶¶ 9-16.)

[19] *See In re Flonase Antitrust Litig.* (*Flonase I*), 610 F. Supp. 2d 409, 415 (E.D. Pa. 2009) (limiting welfare funds' claims to states where the funds have a principal place of business, are located, or otherwise administered); *Ditropan XL*, 529 F. Supp. 2d at 1107 (same); *In re Rezulin Prods. Liab. Litig.*, 392 F. Supp. 2d 597, 611 & n.85 (S.D.N.Y. 2005) (holding that health plans could only bring claims under the laws of the states where their principal places of business were located, and rejecting health plans' efforts to bring claims under state laws where their members acquired the product).

[20] *See, e.g., Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 263 F.R.D. 205, 213 (E.D. Pa. 2009) (dismissing claims under the laws of those states where plans' *(cont'd)*

In this case, Plaintiffs' threadbare, vague allegations leave unanswered questions such as whether Plaintiffs paid a pharmacy or reimbursed a member directly in any state for the cost of the product, or whether they merely reimbursed a third party or parties for those costs. Accordingly, End-Payor Plaintiffs' claims arising under the laws of sates where they do not reside or have a principal place of business must be dismissed.[21]

2. GEHA's Complaint Must Be Dismissed Entirely for Lack of Standing

GEHA's complaint offers even less specificity than that of End-Payor Plaintiffs, and gives no basis to find standing to bring claims based on laws of any state. GEHA alleges that its principal place of business is in Missouri, yet it purports to bring claims for its purchases of Lidoderm under the statutes and common law of fifty states. (GEHA FAC ¶¶ 21, 130, 138, 150, 158, 166-202, 205-218.) Nowhere does GEHA adequately allege that it purchased, reimbursed, or otherwise paid for Lidoderm in *any* state. GEHA asserts that it "purchased a significant amount of branded Lidoderm at monopoly prices during the relevant time period," and that it provides "benefits to nearly 1.5 million covered lives with federal employee members residing in all 50 states as well as the District of Columbia and Puerto Rico." (GEHA FAC ¶¶ 21, 22.) These allegations, which are "merely consistent with" facts that could give rise to standing, are not entitled to an assumption of truth, and deserve no weight in this Court's standing analysis. *See*

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members acquired the product because the complaint did not specifically allege that the plans "sent a reimbursement into a particular state"); *cf. Wellbutrin XL*, 260 F.R.D. at 156 (noting that health plans had specifically alleged injury through the "act of reimbursing their members" in certain states, and so concluding that they had standing for claims under the laws of those states).

[21] As noted, End-Payor Plaintiffs do not allege that they reside or have a principal place of business in twenty-two states—Alabama, Arizona, Arkansas, Colorado, Connecticut, Delaware, Florida, Georgia, Kansas, Kentucky, Maine, Missouri, Nevada, New Hampshire, New Jersey, North Carolina, North Dakota, South Carolina, South Dakota, Tennessee, Texas, and Wisconsin. As to the remaining twenty states—Alaska, District of Columbia, Hawaii, Idaho, Iowa, Louisiana, Maryland, Michigan, Mississippi, Montana, Nebraska, New Mexico, Oklahoma, Oregon, Puerto Rico, Utah, Vermont, Virginia, Washington, and Wyoming—End Payor Plaintiffs allege no connection at all. At a minimum, End-Payor Plaintiffs' claims as to these states should be dismissed.

Iqbal, 556 U.S. at 678 (citation and internal quotation marks omitted).[22] GEHA, therefore, has not alleged injury in, and thus lacks standing to bring claims under the laws of any state other than Missouri—where it is organized and where its principal place of business is located. GEHA's claims under every state except Missouri must be dismissed for lack of Article III standing.

GEHA's Missouri-based claims must also be dismissed because GEHA does not, and cannot, allege a cause of action under federal or state antitrust law. As an indirect purchaser, GEHA does not have standing to bring, and does not allege, claims under federal or Missouri's antitrust law. Instead, based on the same facts as alleged in support of its other state antitrust claims, GEHA asserts: (i) a claim under Missouri's consumer protection statute, and (ii) a claim of unjust enrichment under Missouri law. (GEHA FAC ¶¶ 184, 205-18.) But, as a health insurance provider, GEHA cannot assert a claim under Missouri's consumer protection statute, which provides remedy only for consumers who purchase goods for personal, family, or household use. *See* Mo. Rev. Stat. § 407.025(1); *In re Actimmune Mktg. Litig.*, No. 08-cv-2376, 2010 WL 3463491, at *12 (N.D. Cal. Sept. 1, 2010) (dismissing GEHA's claims under Missouri's consumer protection statute because "the money [] expended to pay for [pharmaecutical products] was for a business purpose, not for a personal, family, or household purpose"), *aff'd*, 464 F. App'x 651 (9th Cir. 2011). GEHA's Missouri-based unjust enrichment claim must also be dismissed because GEHA cannot avoid Missouri's prohibition against damage claims by indirect purchasers and lack of standing under Missouri's consumer protection statute simply by bringing its claim under the common law theory of unjust enrichment. *See Carter v. Alcon Labs., Inc.*, No. 13-cv-0977, 2014 WL 989002, at *5 (E.D. Mo. Mar. 13, 2014) (dismissing unjust enrichment claim after finding that plaintiff failed to state a claim under Missouri's consumer protection statute); *see also In re TFT-LCD (Flat Panel) Antitrust Litig.* (*TFT II*), 599 F. Supp. 2d 1179, 1192 (N.D. Cal. 2009)

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[22] GEHA's allegations that it brings claims under various state statutes "with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm" in any given state, (*see, e.g.*, GEHA FAC ¶¶ 150, 158), are also insufficient to establish standing because GEHA fails to specifically allege that it was a party to a transaction in any particular state. These allegations are vague, conclusory, and "merely consistent with" facts that could give rise to standing. *See Iqbal*, 556 U.S. at 678 (citation and internal quotation marks omitted).

(dismissing unjust enrichment claims where that same claim would be barred under state statutory law); *see also infra* Section V.D.2. For these reasons, and additional reasons discussed below, GEHA's complaint must be dismissed in its entirety.[23]

B. Plaintiffs Fail to State a Claim Under Certain State Antitrust Laws

End-Payor Plaintiffs and GEHA assert claims under the antitrust laws of 29 states. (EPP CAC ¶¶ 168, 181; GEHA FAC ¶¶ 130, 138, 150, 158.) Regardless of whether Plaintiffs have standing to assert these claims, the claims fail for state-specific reasons discussed below.

1. Antitrust Claims Under the Laws of Florida, Massachusetts, Puerto Rico, and Rhode Island Are Barred by the Principles Set Forth in *Illinois Brick*

The Supreme Court has held that indirect purchasers generally may not sue for money damages under Section 4 of the Clayton Act. *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 730, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977). Since the Supreme Court's decision in *Illinois Brick*, some states passed statutes expressly allowing indirect purchasers to recover damages for antitrust violations under state law, so-called *Illinois Brick* repealers. Indirect purchasers, however, cannot assert antitrust claims under the law of states which have not passed such repealers. *In re Terazosin Hydrochloride Antitrust Litig.*, 160 F. Supp. 2d 1365, 1372 (S.D. Fla. 2001).

Here, Plaintiffs lack standing to bring damages claims under the Florida Antitrust Act, the Massachusetts Antitrust Act, and the Puerto Rico Antitrust Act, as none of those statutes permits suits by indirect purchasers.[24] This Court must dismiss Plaintiffs' claims to the extent they arise under those statutes.

This Court should also dismiss Plaintiffs' claims under the Rhode Island Antitrust Act. On

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[23] GEHA's unjust enrichment claim should be dismissed on additional, independent grounds, as set forth below in Section V.D.3.

[24] *In re Static Random Access Memory (SRAM) Antitrust Litig.*, No. 07-md-1819, 2010 WL 5094289, at *4 (N.D. Cal. Dec. 8, 2010) (holding that indirect purchaser claims under Puerto Rico law were foreclosed by *Illinois Brick*); *TFT II*, 599 F. Supp. 2d at 1187-88 (same); *Wellbutrin XL*, 260 F.R.D. 143, 160-61 (E.D. Pa. 2009) (dismissing claims under Florida Antitrust Act as barred under *Illinois Brick*); *Ciardi v. F. Hoffman-La Roche*, Ltd., 762 N.E. 2d 303, 308 (Mass. 2002) (The "rule of law established in *Illinois Brick* [] would apply with equal force to preclude claims brought under G.L. c. 93 by indirect purchasers in Massachusetts."); *Mack v. Bristol–Myers Squibb Co.*, 673 So. 2d 100, 108 (Fla. Dist. Ct. App. 1996).

July 15, 2013, the Rhode Island state legislature enacted a so-called *Illinois Brick*-repealer statute that permits indirect purchasers to seek relief under the Rhode Island Antitrust Act. P.L. 2013, ch. 365, § 1, eff. July 15, 2013, codified at R.I. Gen. Laws § 6-36-7(d). Under Rhode Island law, however, "statutes and their amendments are presumed to apply prospectively." *Hydro-Mfg v. Kayser-Roth*, 640 A.2d 950, 954 (R.I. 1994) (citation omitted). A statute or amendment applies retroactively "[o]nly when it appears by clear, strong language or by necessary implication" that the legislature intended it to apply retroactively. *Id.* at 954-55 (quotation marks and citation omitted); *see also Avanzo v. Rhode Island Dep't of Human Servs.*, 625 A.2d 208, 211 (R.I. 1993) ("As a general rule statutes operate prospectively from and after the effective date of the statute."). There is no suggestion in Rhode Island's repealer statute that the legislature intended it to apply retrospectively.

Where other states have enacted similar *Illinois Brick*-repealers, courts have interpreted those statutes to operate prospectively, unless the statute or the legislative record expressly instructed otherwise. *See, e.g.*, *In re TFT-LCD (Flat Panel) Antitrust Litig.* (*TFT III*), No. 07-md-1827, 10-cv-4346, MDL No. 1827, 2011 WL 1113447, at *2 (N.D. Cal. Mar. 25, 2011) (dismissing claims under Oregon Antitrust Act based on conduct that took place before enactment of repealer statute); *In re Cathode Ray Tube (CRT) Antitrust Litig.*, MDL No. 1917, 2010 WL 9543295, at *14 (N.D. Cal. Feb. 5, 2010) (recommending dismissal of claims under Nebraska and Nevada repealer statutes based on conduct that took place before enactment of repealer statutes); *In re Relafen Antitrust Litig.*, 225 F.R.D. 14, 26 (D. Mass. 2004) (declining to apply Idaho and Arkansas repealer statutes to conduct that occurred prior to enactment). Because the Defendants entered the challenged agreement in May 2012, when plaintiffs had no standing to challenge the agreement under the Rhode Island Antitrust Act, the Court should dismiss Plaintiffs' Rhode Island Antitrust Act claims.

2. End-Payor Plaintiffs' Antitrust Claims Under Illinois Law Fail Because Only the Illinois Attorney General May Bring Indirect Purchaser Class Suits

Under the Illinois Antitrust Act, only the Illinois Attorney General may bring a class action on behalf of indirect purchasers. *See* 740 Ill. Comp. Stat. Ann. § 10/7(2). Courts have dismissed

indirect purchaser class actions under Illinois antitrust law that were not brought by the Illinois Attorney General. *See Gaebler v. N.M. Potash Corp.*, 676 N.E.2d 228, 230 (Ill. App. Ct. 1996) (noting that antitrust actions brought by indirect purchasers are necessarily precluded by section 7(2) of the Illinois Antitrust Act); *see also In re Wellbutrin XL Antitrust Litig.* (*Wellbutrin XL II*), 756 F. Supp. 2d 670, 676-77 (E.D. Pa. 2010) (holding attorney general restriction applicable to indirect purchaser claims under Illinois law); *In re Flonase Antitrust Litig.* (*Flonase II*), 692 F. Supp. 2d 524, 539 (E.D. Pa. 2010) (same). The Court, therefore, should dismiss End-Payor Plaintiffs' claims under the Illinois Antitrust Act.

C. GEHA Fails to State Claims Under State Consumer Protection Laws

GEHA asserts claims under the consumer protection laws of thirty-six states and the District of Columbia, alleging that Defendants engaged in "unfair competition or unfair or deceptive acts or practices." (GEHA FAC ¶¶ 166-202.) The claims are based on the same allegations as those brought under the antitrust laws of several states: that in the context of settling two patent infringement lawsuits, defendants entered into an unlawful settlement agreement that provided for alleged payments to Watson in exchange for Watson's agreement to delay marketing a less expensive generic version of Lidoderm. (GEHA FAC ¶164.) As described in more detail below, most states' consumer protection laws do not address the type of antitrust violations alleged here, and in some instances, expressly bar plaintiffs from repackaging alleged antitrust violations as claims under consumer protection statutes. GEHA's claims that defendants engaged in "deceptive acts or practices," meanwhile, are labels and conclusions that are unsupported by factual allegations.

1. GEHA Cannot Circumvent *Illinois Brick* by Asserting Antitrust Claims Under Consumer Protection Theories

Where a state's antitrust statute does not permit damages suits by indirectly purchasers, in the absence of state authority to the contrary, the Court should not construe state consumer protection statutes as permitting standing for indirect purchasers to bring damages claims in contravention of *Illinois Brick*. Because Alaska's antitrust statute expressly prohibits indirect purchasers from bringing private suits for antitrust violations, courts in this district have repeatedly

held that indirect purchaser plaintiffs are barred from asserting claims under Alaska's consumer protection statute. *In re Static Random Access Memory (SRAM) Antitrust Litig.*, 580 F. Supp. 2d 896, 907 (N.D. Cal. 2008); *In re Dynamic Random Access Memory (DRAM) Antitrust Litig.*, 516 F. Supp. 2d 1072, 1107-08 (N.D. Cal. 2007); *California v. Infineon Technologies AG*, 531 F. Supp. 2d 1124, 1142 (N.D. Cal. 2007). Accordingly, GEHA's claim under Alaska's consumer protection statute must be dismissed.

2. GEHA's Claims Under the Consumer Protection Laws of Several States Fail Because the Laws Do Not Reach Antitrust Violations

The consumer protection laws in Idaho, Kansas, Michigan, Oregon, Pennsylvania, South Dakota, and West Virginia prohibit specific, enumerated activities, and do not reach antitrust violations.[25] For instance, in *DRAM*, this Court held that West Virginia's consumer protection statute does not forbid "traditional antitrust conduct—*e.g.*, price-fixing and market allocation . . . or conduct otherwise constituting a horizontal or vertical restraint on trade or commerce." 516 F. Supp. 2d at 1118. Where state consumer protection statutes do not forbid traditional antitrust conduct, several courts have dismissed claims arising under those statutes. *In re Flash Memory Antitrust Litigation*, 643 F. Supp. 2d 1133, 1159, 1162 (N.D. Ca. 2009) (dismissing claims under Maine and West Virginia law because consumer protection statutes did not reach alleged antitrust violations); *DRAM*, 516 F. Supp. 2d at 1110-18 (same, as to Idaho, Oregon and West Virginia law because statutes banned enumerated activities only and not antitrust conduct); *GPU 1*, 527 F. Supp. 2d at 1030 (same, as to Oregon and West Virginia); *In re New Motor Vehicles Can. Exp. Antitrust Litig.* (*NMV*), 350 F. Supp. 2d 160, 189, 200-03 (D. Me. 2004) (same, as to Michigan, Pennsylvania, and South Dakota); *see also In re Static Random Access Memory (SRAM) Antitrust Litig.*, No. 07-md-01819, 2010 WL 5094289, at *9 (N.D. Cal. Dec. 8, 2010) (holding that Kansas consumer protection statute did not reach alleged antitrust violations). For this reason, the Court should dismiss GEHA's consumer protection claims under Idaho, Kansas, Michigan, Oregon, Pennsylvania, South Dakota, and West Virginia laws.

[25] Idaho Code Ann. § 48-603; Kan. Stat. Ann. § 50-623, *et seq.*; Mich. Comp. Laws Ann. § 445.903; Or. Rev. Stat. Ann. § 646.605, *et seq.*; 73 Pa. Stat. § 201-1, *et seq.*; S.D. Codified Laws § 37-24-1, *et seq.*; W. Va. Code Ann. § 46A-6-101, *et seq.*

Similarly, in the absence of authority from Arkansas's highest court, courts in this district have repeatedly dismissed claims based on antitrust conduct when brought under Arkansas's consumer protection law. *In re TFT-LCD (Flat Panel) Antitrust Litig.* (*TFT IV*), 787 F. Supp. 2d 1036, 1042 (N.D. Cal. 2011); *In re Static Random Access Memory (SRAM) Antitrust Litig.*, 2010 WL 5094289, at *8 (citing *GPU I*, 527 F. Supp. 2d at 1029-30); *In re TFT-LCD (Flat Panel) Antitrust Litig.* (*TFT I*), 586 F. Supp. 2d 1109, 1125 (N.D. Cal. 2008). Accordingly, GEHA's Arkansas consumer protection claim should also be dismissed.

3. Business Entities May Not Bring Claims Under the Consumer Protection Laws of Several States

The consumer protection laws of the District of Columbia, Hawaii, Maine, Missouri, Montana, and Pennsylvania provide remedies only for consumers who purchase goods for personal, family, or household use.[26] In these states, claims brought by entities that purchase goods for business purposes are subject to dismissal. *See, e.g.*, *In re Actimmune Mktg. Litig.*, 2010 WL 3463491, at *12 (dismissing Missouri consumer protection claims); *TFT I*, 586 F. Supp. 2d at 1128-29 (dismissing claims under Pennsylvania consumer protection statute for failure to plead that plaintiffs' purchases were made primarily for personal, family, or household purposes); *DRAM*, 516 F. Supp. 2d at 1113 (same, as to Montana); *see also Shaw v. Marriott Int'l, Inc.*, 605 F.3d 1039, 1044 (D.C. Cir. 2010) (affirming summary judgment under District of Columbia consumer protection statute because plaintiff's employees did not engage in consumer transactions that were "primarily for personal, household, or family" reasons).

Similarly, under Kansas's consumer protection statute, only a "[c]onsumer," *i.e.*, an "individual, husband, wife, sole proprietor or family partnership," has standing to pursue a private remedy. Kan. Stat. Ann. §§ 50-634, 50-624(b). A corporation does not. *Kestrel Holdings I, L.L.C. v. Learjet Inc.*, 316 F. Supp. 2d 1071, 1076-77 (D. Kan. 2004); *Martin v. Ford Motor Co.*, 292 F.R.D. 252, 278-79 (E.D. Pa. 2013) ("The only business entities that can bring suit under the Kansas Consumer Protection Act are those organized as sole proprietors or family partnerships.").

[26] D.C. Code § 28-3901(2); Haw. Rev. Stat. § 480-1 and 2(d); Me. Rev. Stat. tit. 5, § 213(1); Mo. Rev. Stat. § 407.025; Mont. Code Ann. §§ 30-14-102(1), 30-14-133; 73 Pa. Stat. Ann. § 201-9.2.

As a corporation providing health insurance, (GEHA FAC ¶ 21), GEHA does not and cannot allege that it purchased Lidoderm or generic Lidoderm primarily for personal, household, or family use. Nor does it allege that it is a consumer as that term is defined under Kansas law. Accordingly, GEHA's consumer protection claims under the District of Columbia, Hawaii, Kansas, Maine, Missouri, Montana, and Pennsylvania law must be dismissed.

Under Massachusetts law, business entities can maintain consumer protection claims, but not if they are indirect purchasers. In Massachusetts, an entity engaged "in the conduct of any trade or commerce" may only assert consumer protection claims under Section 11 of Massachusetts General Law ch. 93A. *Cont'l Ins. Co. v. Bahnan*, 216 F.3d 150, 156 (1st Cir. 2000); *see also In re TJX Cos. Retail Sec. Breach Litig.*, 564 F.3d 489, 495 (1st Cir. 2009). But, Section 11 similarly has not been extended to indirect purchasers. Rather, under Section 11, "the court shall . . . be guided in its interpretation of unfair methods of competition by those provisions of chapter ninety-three known as the Massachusetts Antitrust Act." Because "the *Illinois Brick* approach is taken under the Massachusetts Antitrust Act and [Section 11 of the Massachusetts Consumer Protection Act]," *Ciardi v. F. Hoffman-La Roche, Ltd.*, 762 N.E.2d 303, 321 (Mass. 2002), business entities that are indirect purchasers are barred from maintaining claims. In this case, each of the named Plaintiffs that asserts a claim under Massachusetts law is an indirect purchaser whose Section 11 claim is barred under the principles set forth in *Illinois Brick*.[27] *See In re Cathode Ray Tube (CRT) Antitrust Litig.*, MDL 1917, 2014 WL 1088256, at *3 (N.D. Cal. Mar. 13, 2014).

[27] Note that this applies both to End-Payor Plaintiffs and GEHA. Whereas Section 11 is reserved for business entities, section 9 of Mass. Gen. Law Ch. 93A is reserved for individual consumers and "affords no relief to persons engaged in trade or commerce." *Cont'l Ins. Co. v. Bahnan*, 216 F.3d 150, 156 (1st Cir. 2000). None of the named Plaintiffs that allegedly resides in or purchased, reimbursed, or otherwise paid for Lidoderm or generic Lidoderm in Massachusetts is an individual consumer under the Act.

4. GEHA Has Failed to Adequately Plead Deceptive Acts or Practices[28]

GEHA's allegations of deceptive conduct are "labels and conclusions" that do not pass muster under Rule 8(a), let alone Rule 9(b). *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). GEHA alleges that Defendants "(a) wrongfully conduct[ed] baseless litigation to trigger the automatic 30-month stay prohibiting FDA from granting final approval permitting Actavis to market its less-expensive authorized generic version of Lidoderm." (GEHA FAC ¶ 164.) GEHA's FAC does not, however, include any facts to support the allegation that the patent litigation was baseless. *See, e.g.*, *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380, 404 (E.D. Pa. 2010) (allegations of misstated patent applications and sham litigation did not state a claim under Arizona's Consumer Fraud Act). GEHA also describes the terms of Defendants' settlement agreement, alleging that defendants:

> (b) enter[ed] into the Reverse Payment Agreement whereby Endo agreed to pay Actavis in exchange for Actavis' commitment to postpone marketing its generic version of Lidoderm; (c) compensat[ed] Actavis at least $96 million in free product under the Reverse Payment Agreement; and [(d)] agree[d] not to compete against Actavis with Endo's own authorized generic Lidoderm.

(GEHA FAC ¶ 164.) GEHA's description of the Defendants' settlement agreement includes the term "Reverse Payment Agreement," but it does not include any facts that support the allegation that Defendants engaged in deceptive or fraudulent conduct. GEHA's claims under all state consumer protection laws fail to the extent they rely on a theory of deceit or fraud.

Under the consumer protection laws of several states, moreover, failure to plead (1) deceit or fraud; (2) conduct directed to consumers; or (3) reliance is fatal. Under the consumer protection laws of Arizona, Maine, Minnesota, New Mexico, New York, and South Dakota, a plaintiff must

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[28] Under Fed. R. Civ. P. 9(b), plaintiffs must plead "with particularity the circumstances constituting fraud or mistake." Rule 9(b)'s heightened pleading requirement applies to claims under consumer protection statutes that include deceptive or fraudulent conduct as an element of the claim. *See, e.g.*, *Burton v. R.J. Reynolds Tobacco Co.*, 884 F. Supp. 1515, 1524 (D. Kan. 1995) (Rule 9(b) applies to deceptive trade practices claims under Kansas law); *E-Shops Corp. v. U.S. Bank Nat'l Ass'n*, 795 F. Supp. 2d 874, 879 (D. Minn. 2011) (same, under Minnesota law).

plead deceit or fraud.[29] New York's consumer protection law requires that the allegedly deceptive act or practice be directed to consumers.[30] Meanwhile, the laws in Arizona, Idaho, Maine, and Michigan require that a plaintiff relied on deceptive conduct when making their purchase.[31] GEHA has failed to allege that Defendants engaged in a deceptive or fraudulent act, that such an act was directed to consumers, or that it relied on any such act. GEHA's claims under the consumer protection laws of Arizona, Idaho, Maine, Minnesota, New Mexico, New York, and South Dakota must therefore be dismissed.

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[29] Ariz. Rev. Stat. Ann. § 44-1522, *et seq.*; 5 Maine Rev. Stat. § 207, *et seq.*; Minn. Stat. § 325D.43, *et seq.*; New Mexico Stat. Ann. §§ 57-12-1, *et seq.*; New York General Business Law § 349, *et seq.*; South Dakota Codified Laws § 37-24-1, *et seq.*; *Flonase II*, 692 F. Supp. 2d at 536 ("[A]llegations of deception, and not merely of unfair acts, are required to state a claim under the [Arizona Consumer Fraud Act].") (citing cases); *Tungate v. MacLean-Stevens Studios, Inc.*, 714 A.2d 792, 797 (Me. 1997) (noting that where the allegation is unfair pricing, "the inquiry is whether the price has the effect of deceiving the consumer, or inducing her to purchase something that she would not otherwise purchase"); *In re Auto. Refinishing Paint Antitrust Litig.*, 515 F. Supp. 2d 544, 555 (E.D. Pa. 2007) (dismissing claims under New York's consumer protection law for failure to plead deceptive conduct); *NMV*, 350 F. Supp. 2d at 189-90, 202-03 (dismissing claims under Minnesota and South Dakota consumer protection statutes for failure to plead deception); *Nw. Pub. Serv. v. Union Carbide Corp.*, 236 F. Supp. 2d 966, 973-74 (D.S.D. 2002) (holding that claim under South Dakota's consumer protection statute requires "proof of an intentional misrepresentation or concealment of a fact on which plaintiff relied and that caused an injury to plaintiff").

Moreover, failure to disclose allegedly anticompetitive conduct is not, in itself, a deceptive act. *See, e.g.*, *In re Graphics Processing Units Antitrust Litig.* (*GPU II*), 540 F. Supp. 2d 1085, 1100-01 (N.D. Cal. 2007) (dismissing consumer protection claims for failure to plead a deceptive practice apart from the anticompetitive conduct itself); *NMV*, 350 F. Supp. 2d at 178, 190-91, 195, 197 (holding that failure to disclose antitrust conspiracy was not "false or deceptive act" under Arkansas, Missouri, New Mexico, and New York consumer protection laws).

[30] *Paltre v. Gen. Motors Corp.*, 26 A.D.3d 481, 483 (N.Y. App. Div. 2006); *DRAM*, 516 F. Supp. 2d at 1114; *see Wellbutrin XL*, 260 F.R.D. at 164 (holding indirect purchasers injuries too remote in light of requirement that deceptive act be directed toward consumers) (citing *Blue Cross and Blue Shield of N.J., Inc. v. Phillip Morris USA Inc.*, 818 N.E.2d 1140, 1143 (N.Y. 2004)); *New York v. Daicel Chem. Indus.*, Ltd., 42 A.D.3d 301, 304, 840 N.Y.S.2d 8 (N.Y. App. Div. 2007) (same).

[31] Ariz. Rev. Stat. Ann. § 44-1522, *et seq.*; Idaho Code § 48-601, *et seq.*; 5 Maine Rev. Stat. § 207, *et seq.*; Michigan Comp. Laws Ann. § 445.901, *et seq.*; *see Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380, 411 (E.D. Pa. 2010) (dismissing claims under Arizona, Idaho, and Michigan law); *GPU I*, 527 F. Supp. 2d at 1031 (same, under Maine law, holding supra-competitive prices could not induce plaintiffs into making purchases) (citing *Tungate v. Maclean-Stevens Studios, Inc.*, 714 A.2d 792 (Me. 1998)).

5. GEHA Has Failed to Allege Primarily Intrastate Conduct for Consumer Protection Statutes That Require Such Conduct

Some states' consumer protection laws require that claims arise from purely or primarily intrastate, rather than nationwide, conduct.

New Hampshire. New Hampshire's consumer protection law requires that the alleged unfair or deceptive act took place within New Hampshire. N.H. Rev. Stat Ann. § 358-A.2; *Precourt v. Fairbank Reconstruction Corp.*, 856 F. Supp. 2d 327, 343-44 (D.N.H. 2012); *see also Wilcox Indus. Corp. v. Hansen*, 870 F.Supp.2d 296, 305 (D.N.H. 2012) (dismissing consumer protection claim where there was "simply no allegation that any offending conduct occurred in New Hampshire"); *accord In re Refrigerant Compressors Antitrust Litig.*, 2:09-md-2042, 2013 WL 1431756, at *17-18 (E.D. Mich. Apr. 9, 2013); *In re Flash Memory Antitrust Litig.*, 643 F. Supp. 2d 1133, 1159 (N.D. Ca. 2009); *Mueller Co. v. U.S. Pipe & Foundry Co.*, No. 03-cv-0170, 2003 WL 22272135, at *5-6 (D.N.H. 2003). GEHA does not allege that any of the Defendants' conduct took place in New Hampshire. Therefore its New Hampshire consumer protection claims must be dismissed.

New York. New York General Business Law § 349 "unambiguously evinces a legislative intent to address commercial misconduct occurring within New York," and to be a prohibited act under the statute, "the deception of a consumer must occur in New York." *Goshen v. Mut. Life Ins. Co.*, 774 N.E.2d 1190, 1195 (N.Y. 2002); *see also Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC,* 263 F.R.D. 205, 214 (E.D. Pa. 2009) (dismissing claim because alleged deceptive conduct neither took place in New York nor was directed at consumers). GEHA does not allege that any of the Defendants' conduct took place in New York, nor does it allege that any "deceptive" transaction that it participated in took place in New York.

North Carolina. To state a claim under the North Carolina's consumer protection statute, a plaintiff must allege that defendants' conduct had a substantial effect on in-state business. *Merck & Co. v. Lyon*, 941 F. Supp. 1443, 1463 (M.D.N.C. 1996) (dismissing claim where "plaintiffs . . . failed to allege a substantial effect on any in-state business operations)," and "[a]ny injury plaintiffs may suffer in North Carolina will be incidental"); *see also Refrigerant Compressors*,

2013 WL 1431756, at *19 (holding that inflated prices resulting from alleged antitrust conspiracy constituted an "incidental" rather than a "substantial" in-state injury as required under North Carolina's consumer protection statute). GEHA's claim under North Carolina's consumer protection statute must be dismissed because GEHA does not allege any facts showing that Defendants' conduct took place in or had a substantial effect on in-state business in North Carolina.

D. Plaintiffs' Unjust Enrichment Claims Should Be Dismissed

1. Plaintiffs Cannot Bring Either Autonomous or Parasitic Unjust Enrichment Claims

Plaintiffs do not specify whether their unjust enrichment claims are "autonomous"—*i.e.*, independent of their antitrust or consumer protection claims—or "parasitic"—*i.e.*, merely asserting an alternative remedy for their underlying predicate antitrust and consumer protection claims. *See Flonase II*, 692 F. Supp. 2d at 542 n.13 (E.D. Pa. 2010). Under either theory Plaintiffs cannot evade federal and state law standing restrictions by resorting to the doctrine of unjust enrichment.

First, if Plaintiffs are asserting an autonomous claim, then it must fail because Plaintiffs cannot use an unjust enrichment claim to circumvent state antitrust and consumer protection laws. *See NMV*, 350 F. Supp. 2d 160, 209-10 (dismissing all autonomous unjust enrichment claims); *see also Flonase II*, 692 F. Supp. 2d at 542 n.13. Autonomous unjust enrichment claims are problematic because "[t]he premise for such a claim must be that, even if the defendants' conduct is blameless under the substantive requirements of federal and state antitrust statutes and state consumer protection statutes, the plaintiffs nevertheless can still obtain restitution." *NMV*, 350 F. Supp. 2d at 209. Allowing such a result "would undermine state legislative policies and an entire body of substantive law." *Flonase II*, 692 F. Supp. 2d at 542 n.13. Allowing Plaintiffs to pursue autonomous unjust enrichment claims would circumvent the common-law and statutory schemes that have been designed to address the conduct at issue.

Second, if Plaintiffs are asserting a parasitic claim, then that must fail for the same reasons that the underlying antitrust and consumer protection claims fail. *See id.*; *Steamfitters Loc. Union No. 420 Welfare Fund v. Phillip Morris, Inc.*, 171 F.3d 912, 937 (3d Cir. 1999) (affirming dismissal of unjust enrichment claims where dismissal of antitrust, RICO, and traditional tort

claims also were affirmed on appeal). While both GEHA and End-Payor Plaintiffs purport to assert unjust enrichment under the laws of 48 states, the District of Columbia, and Puerto Rico, those claims are wholly tethered to their antitrust or consumer protection claims. To the extent that Plaintiffs' state antitrust and consumer protection claims are dismissed, the corresponding unjust enrichment claims also must be dismissed.

2. Plaintiffs Cannot Use Unjust Enrichment to Avoid *Illinois Brick*

When a plaintiff is precluded from seeking damages under a claim at law, that plaintiff may not seek those same damages through an equitable claim of restitution. *See INS v. Pangilinan*, 486 U.S. 875, 883 (1988) ("[C]ourts of equity can no more disregard statutory and constitutional requirements and provisions than can courts of law"). As discussed in Section V.B.1, *Illinois Brick* prohibited indirect purchasers from bringing federal antitrust damages claims. Various states adhere to *Illinois Brick's* rule precluding indirect purchaser damages actions under state antitrust laws, which reflects state legislatures' public policy choices regarding economic conduct. *See HyPoint Tech., Inc. v. Hewlett-Packard Co.*, 949 F.2d 874, 877 (6th Cir. 1991) ("Antitrust laws reflect considered policies regulating economic matters"). Plaintiffs cannot circumvent these legislative policy choices by repackaging antitrust theories under the common law of unjust enrichment. When state law bars an antitrust action by indirect purchasers, "[a]llowing indirect purchasers to recover and recoup a benefit from the defendant under an unjust enrichment theory would circumvent the policy choice of *Illinois Brick*." *Flonase II*, 692 F. Supp. 2d at 542.[32] To do so would "subvert the statutory scheme to allow these same indirect purchasers to secure, for the statutory violation, restitutionary relief at common law (or in equity)." *NMV*, 350 F. Supp. 2d at 211. Unless a state has expressly passed *Illinois Brick* repealer legislation or interpreted their laws to override *Illinois Brick*, it should be presumed that the state has decided to follow the *Illinois*

[32] *See also In re Terazosin Hydrochloride Antitrust Litig.*, 160 F. Supp. 2d 1365, 1380 (S.D. Fla. 2001) ("State legislatures and courts that adopted the *Illinois Brick* rule against indirect purchaser antitrust suits did not intend to allow an end run around the policies allowing only direct purchasers to recover"); *TFT II*, 599 F. Supp. 2d at 1191 (recognizing that "a number of cases ... stand for th[e] general proposition" that indirect purchasers "may not circumvent the restrictions on antitrust claims under [certain states] by reframing those claims as unjust enrichment actions").

Brick limitation on indirect purchaser claims. *See, e.g.*, *TFT II*, 599 F. Supp. 2d at 1185-87; *FTC v. Mylan Labs., Inc.*, 62 F. Supp. 2d 25, 43 (D.D.C. 1999).

Plaintiffs have asserted unjust enrichment claims under the laws of all 50 states. However, 23 states and Puerto Rico have expressly or implicitly adopted the holding in *Illinois Brick* and disallow indirect payor actions. These states are: Alaska, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Kentucky, Louisiana, Maryland, Massachusetts, Missouri, Montana, New Jersey, Oklahoma, Pennsylvania, Puerto Rico, Rhode Island,[33] South Carolina, Texas, Virginia, Washington, and Wyoming. *See* App. 4 (collecting authority for states following *Illinois Brick*). Because these states do not recognize indirect purchaser actions, the unjust enrichment claims based on these state laws must be dismissed.

3. Plaintiffs' Unjust Enrichment Claims Fail For Other Deficiencies Under State Law

Apart from the general impediments to Plaintiffs' unjust enrichment claim, various states impose specific requirements that plaintiffs must plead to sustain such a claim. *See In re Packaged Ice Antitrust Litig.*, 779 F. Supp. 2d 642, 667 (E.D. Mich. 2011) ("State law requirements under unjust enrichment law vary widely"). Plaintiffs make no effort to meet the pleading requirements of each state, and their unjust enrichment claims fail for three reasons: (1) Plaintiffs received the benefit of their bargain with Defendants; (2) Defendants provided consideration for the benefit they received; and (3) Plaintiffs did not directly benefit from any transaction involving Defendants.

(i) Plaintiffs Received The Benefit Of Their Bargains

Courts in Arizona, Arkansas, California, the District of Columbia, Florida, Illinois, Iowa, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, and Utah ("Benefit of the Bargain States") reject unjust enrichment claims when "parties voluntarily have negotiated, entered into and fully performed their bargain." *See NMV*, 350 F. Supp. 2d at 210; *see also* Rstmt. (First) of Restitution § 107(1) (1937). There can be no unjust enrichment where

[33] As noted above, Rhode Island's so-called *Illinois Brick*-repealer statute enacted in July 2013, more than a year after defendants entered into the allegedly unlawful settlement agreement at issue in this case, should not be applied retrospectively. *See supra* Section V.B.1.

Plaintiffs obtained the product they expected at the price they agreed to pay—*i.e.*, the benefit of his bargain.

Plaintiffs do not allege that they failed to receive the benefit of their bargain—Lidoderm or generic Lidoderm—at an agreed upon price. Nor do they allege that they sought to rescind their purchases. Rather, Plaintiffs only assert that they overpaid for the products for which they bargained. (EPP CAC ¶ 31 (Plaintiffs and class members "paid artificially inflated prices for lidocaine patch 5% and were deprived of the benefits of competition from less-expensive generic versions of Lidoderm as a result of Defendants' wrongful conduct"); GEHA FAC ¶ 113 ("Defendants' unlawful concerted action delayed the sale of generic Lidoderm in the United States, causing GEHA to overpay for Lidoderm at artificially inflated, supra-competitive prices").) That assertion is insufficient to sustain an unjust enrichment claim because Plaintiffs obtained the products they bargained for at the prices they agreed to pay. *See, e.g.*, *In re Intel Corp. Microprocessor Antitrust Litig.*, 496 F. Supp. 2d 404, 421 (D. Del. 2007) (rejecting unjust enrichment claims for overpayment of microprocessors by indirect purchasers where class plaintiffs "paid the purchase price for their computers and received their computers," "ha[d] not sought to rescind their purchases," and "ha[d] not alleged that they did not receive the benefit of their bargain"); *see also Dist. 1199P Health & Welfare Plan v. Janssen, LP*, 784 F. Supp. 2d 508, 532-33 (D.N.J. 2011); *Prohias v. Pfizer ("Prohias I")*, 485 F. Supp. 2d 1329, 1335 (S.D. Fla. 2007); *See* App. 5 (collecting authority for each Benefit of the Bargain State). For these reasons, Plaintiffs' unjust enrichment claims fail in the Benefit of the Bargain States.

(ii) Defendants Provided Consideration In Exchange For Any Benefits Received

Florida, Kansas, Massachusetts, Missouri, Nevada, New Hampshire, South Dakota, Tennessee, Utah, Vermont, and Wisconsin (the "Consideration States") do not permit unjust enrichment claims where the defendant has provided consideration for the benefit it received. In these states, retention of the benefit under such circumstances is not considered "unjust." *See* App. 5 (collecting authority for each Consideration State). Here, Plaintiffs received consideration—namely, in the form of lidocaine patch 5%—in exchange for the price of the product, which is the

only benefit that Plaintiffs allege Defendants received, albeit indirectly. Thus, Plaintiffs may not bring unjust enrichment claims in the Consideration States.

(iii) Plaintiffs Fail to Allege a Relationship With Defendants Leading to a Direct Benefit

Twenty states ("Direct Benefit States") require that a plaintiff directly confer a benefit upon the defendant for which restitution must be provided;[34] an indirect benefit of revenue from the indirect purchase of a drug product will not suffice. *See*, *e.g.*, *In re Plavix Indirect Purchaser Antitrust Litig.*, No. 1:06-cv-226, 2011 WL 335034, at *7 (S.D. Oh. Jan. 31, 2011) ("Any payment by Indirect Purchasers for Plavix was not a 'benefit conferred' but instead consideration for the patented drug"); *In re Aftermarket Filters Antitrust Litig.*, No. 08-CV-4883, 2010 WL 1416259, at *2-3 (N.D. Ill. Apr. 1, 2010) ("plaintiffs are unable to allege that they have conferred a benefit on defendants. . . . Any benefit that plaintiffs have conferred, however, would be on others in the chain of distribution from whom they purchased, not on defendants"). In these states, Plaintiffs must allege that they conferred some "direct" advantage on Defendants. However, the End-Payor Plaintiffs and GEHA expressly exclude individuals or entities who directly purchased or interacted with Defendants or their affiliates from their Complaints. (EPP CAC ¶ 29(c); *see generally* GEHA FAC (omitting any allegations of direct dealings with any of the Defendants)). These allegations are insufficient to meet the pleading standards applicable in each state that has adopted this "direct benefit" rule. Consequently, Plaintiffs' unjust enrichment claims in these states must be dismissed.

(iv) Unjust Enrichment Claims Purportedly Brought Under California Law Should Be Dismissed

In addition to the above defects, Plaintiffs' California unjust enrichment claim must fail because California does not recognize a cause of action for unjust enrichment. *In re iPhone Application Litig.*, 844 F. Supp. 2d 1040, 1075 (N.D. Cal. 2012) ("Unjust enrichment is not a cause of action, [it is] just a restitution claim." (alternations and quotation marks omitted)); *Hill v. Roll*

[34] These states are Alabama, Arizona, the District of Columbia, Florida, Georgia, Idaho, Kansas, Maine, Maryland, Michigan, Missouri, New Jersey, New York, North Carolina, North Dakota, Pennsylvania, Rhode Island, South Carolina, Texas, and Utah. *See* App. 5 (collecting authority for each Direct Benefit State).

Int'l Corp., 195 Cal. App. 4th 1295, 1307 (2011) (noting that unjust enrichment is merely a form of restitution); *Levine v. Blue Shield of Cal.*, 189 Cal. App. 4th 1117, 1138 (2010) (observing that unjust enrichment does not state a claim); *Walker v. USAA Cas. Ins. Co.*, 474 F. Supp. 2d 1168, 1174 (E.D. Cal. 2007) ("Because California law does not recognize Plaintiff's claim for unjust enrichment, there are no facts Plaintiff could prove to support this claim."), *aff'd sub nom. Walker v. Geico Gen. Ins. Co.*, 558 F.3d 1025 (9th Cir. 2009); *Fraley v. Facebook*, 830 F. Supp. 2d 785, 814 (N.D. Cal. 2011) (dismissing the plaintiffs' unjust enrichment claim because it failed to state a cause of action). Accordingly, the Court should dismiss End-Payor Plaintiffs' and GEHA's unjust enrichment claims under California law.

CONCLUSION

For the foregoing reasons, the Court should dismiss Plaintiffs' claims with prejudice.

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Respectfully submitted,

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